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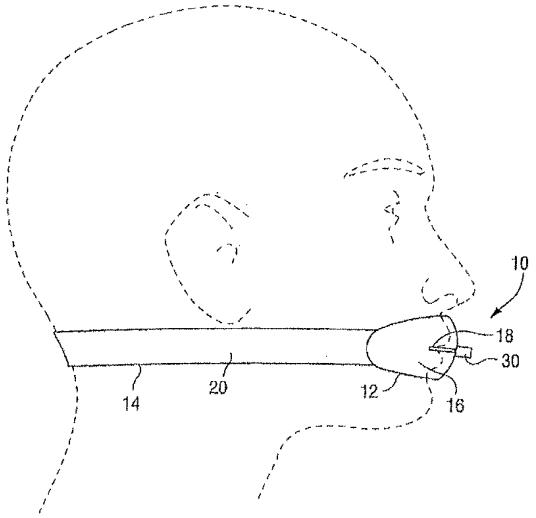
(54) Title: MOUTH SEAL ASSEMBLY FOR NASAL MASK SYSTEM



(57) Abstract: A mouth seal assembly (10) for use with a nasal mask system includes a mouth seal (12) adapted to form a seal with the patient's mouth. The mouth seal (12) is substantially independent from a supply of pressurized air from the nasal mask system. An anti-asphyxia valve (30) may be provided to either the mouth seal (12) over the patient's lips or the nasal mask system. A strap arrangement (14) may support the mouth seal (12) in a desired position on the patient's face in use.

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MOUTH SEAL ASSEMBLY FOR NASAL MASK SYSTEM

CROSS-REFERENCE TO PRIORITY APPLICATION

[0001] This application claims the benefit of U.S. Provisional Application No. 60/711,669, filed August 29, 2005, which is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

[0002] The present invention relates to a mouth seal assembly for use with a nasal mask system for Non-invasive Positive Pressure Ventilation (NIPPV) and for continuous positive airway pressure (CPAP) therapy of sleep disordered breathing (SDB) conditions such as obstructive sleep apnea (OSA).

BACKGROUND OF THE INVENTION

[0003] Treatment of sleep disordered breathing (SDB), such as obstructive sleep apnea (OSA), by continuous positive airway pressure (CPAP) mask systems involves the continuous delivery of air (or other breathable gas) pressurized above atmospheric pressure to the airways of a human or other mammalian patient via a conduit and a mask. Typically, the mask fits over the nose and/or mouth of the patient. Pressurized air flows to the mask and to the airways of the patient via the nose and/or mouth. As the patient exhales, carbon dioxide gas may collect in the mask. A washout vent in the mask or conduit discharges the exhaled gas from the mask atmosphere.

[0004] When nasal mask systems are used, e.g., nasal masks or nozzle assemblies, some patients have a tendency for mouth leak. Alternatively, some patients may have a tendency for mouth breathing when using a nasal mask system. When air escapes through the patient's mouth, the patient does not obtain the full benefit of the delivered treatment pressure. Therefore, the effectiveness of CPAP therapy is diminished. In addition, mouth leak may result in noise, increased treatment pressure to compensate for the leak, increased load on the nasal passages, nasal obstruction, and/or runny nose, for example. The reduction of mouth

leak and the prevention of mouth breathing encourage nasal breathing which may prove beneficial for the patient.

[0005] PCT Application No. PCT/AU2004/001832 and U.S. Patent Nos. 1,873,160, 5,560,354, 6,123,082, and 6,571,798 disclose devices that attempt to reduce mouth leak.

SUMMARY OF THE INVENTION

[0006] One aspect of the invention relates to a mouth seal assembly for use with a nasal mask system that eliminates or at least minimizes mouth leak.

[0007] Another aspect of the invention relates to a mouth seal assembly for use with a nasal mask system that eliminates mouth breathing.

[0008] Another aspect of the invention relates to a mouth seal assembly for use with a nasal mask system. The mouth seal assembly includes a mouth seal adapted to form a seal with the patient's mouth. The mouth seal is substantially independent from a supply of pressurized air from the nasal mask system. An anti-asphyxia valve is provided to the mouth seal over the patient's lips.

[0009] Yet another aspect of the invention relates to a nasal mask system including a nasal mask structured to form a seal with the patient's nose and deliver a supply of pressurized air and a mouth seal assembly attached to the nasal mask. The mouth seal assembly includes a mouth seal adapted to form a seal with the patient's mouth. The mouth seal is substantially independent from the supply of pressurized air. An anti-asphyxia valve is provided to the mouth seal over the patient's lips.

[0010] Still another aspect of the invention relates to a mouth seal assembly for use with a nasal mask system. The mouth seal assembly includes a substantially rigid tube adapted to form a seal with the patient's lips. The tube is substantially independent from a supply of pressurized air from the nasal mask system. A strap arrangement supports the tube in a desired position on the patient's face in use.

[0011] Still another aspect of the invention relates to a nasal mask system including a nasal mask structured to form a seal with the patient's nose and deliver a supply of pressurized air and a mouth seal adapted to form a seal with the patient's mouth. The nasal mask includes a nasal assembly structured to sealingly communicate with nasal passages of the patient's nose in use and headgear provided to the nasal assembly to maintain the nasal

assembly in a desired position on the patient's face. The mouth seal is substantially independent from the supply of pressurized air. The nasal assembly and/or headgear supports the mouth seal in position on the patient's face.

[0012] Still another aspect of the invention relates to a mouth seal assembly for use with a nasal mask system. The mouth seal assembly includes a mouth seal adapted to form a seal with the patient's mouth and a mount provided to the mouth seal and adapted to support the mouth seal on the nasal mask system. The mouth seal is substantially independent from a supply of pressurized air from the nasal mask system. The mouth seal is formed with foam to provide a foam seal or interface with the patient's mouth in use.

[0013] Still another aspect of the invention relates to a nasal mask system including a nasal mask structured to form a seal with the patient's nose and deliver a supply of pressurized air and a mouth seal assembly provided to the nasal mask. The mouth seal assembly includes a mouth seal adapted to form a seal with the patient's mouth and a mount adapted to support the mouth seal on the nasal mask. The mouth seal includes a spring, bellows or gusset arrangement that provides the mouth seal with a sealing force onto the patient's mouth in use.

[0014] Other aspects, features, and advantages of this invention will become apparent from the following detailed description when taken in conjunction with the accompanying drawings, which are a part of this disclosure and which illustrate, by way of example, principles of this invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] The accompanying drawings facilitate an understanding of the various embodiments of this invention. In such drawings:

[0016] Fig. 1 is a side view of a mouth seal assembly according to an embodiment of the present invention;

[0017] Fig. 2 is a front view of the mouth seal assembly shown in Fig. 1;

[0018] Fig. 3 is a side view of the mouth seal assembly shown in Fig. 1 being used in conjunction with a nasal mask system;

[0019] Fig. 4 is a front view of the mouth seal assembly and nasal mask system shown in Fig. 3;

[0020] Fig. 5 is a side view of a mouth seal assembly according to another embodiment of the present invention;

[0021] Fig. 6 is a front view of the mouth seal assembly shown in Fig. 5;

[0022] Fig. 7 is a perspective view of a mouth seal assembly according to another embodiment of the present invention, the mouth seal assembly being used in conjunction with a nasal mask system;

[0023] Fig. 8 is a side view of the mouth seal assembly and nasal mask system shown in Fig. 7;

[0024] Fig. 9 is a top view of the mouth seal assembly shown in Fig. 7 isolated from the nasal mask system;

[0025] Fig. 10 is a rear view of the mouth seal assembly shown in Fig. 7 isolated from the nasal mask system;

[0026] Fig. 11 is a perspective view of a mouth seal assembly according to another embodiment of the present invention, the mouth seal assembly being used in conjunction with a nasal mask system;

[0027] Fig. 12 is a side view of a mouth seal assembly according to yet another embodiment of the present invention, the mouth seal assembly being used in conjunction with a nasal mask system;

[0028] Fig. 13 is a side view of the mouth seal assembly and nasal mask system shown in Fig. 12 removed from the patient's head;

[0029] Fig. 14 is a rear view of the mouth seal assembly and nasal mask system shown in Fig. 12 removed from the patient's head;

[0030] Fig. 15 is a perspective view of a mouth seal assembly according to still another embodiment of the present invention, the mouth seal assembly being used in conjunction with a nasal mask system;

[0031] Fig. 16 is a side view of the mouth seal assembly and nasal mask system shown in Fig. 15;

[0032] Figs. 17-20 are various views of a mouth seal assembly according to another embodiment of the present invention, the mouth seal assembly being used in conjunction with a nasal mask system;

[0033] Figs. 21-23 are various views of a mouth seal assembly according to another embodiment of the present invention, the mouth seal assembly being used in conjunction with a nasal mask system;

[0034] Fig. 24 is a side view of a mouth seal assembly according to another embodiment of the present invention, the mouth seal assembly being used in conjunction with a nasal mask system;

[0035] Fig. 25 is a side view of a mouth seal according to another embodiment of the present invention; and

[0036] Figs. 26-30 are top views of mouth seals according to alternative embodiments of the present invention.

DETAILED DESCRIPTION OF ILLUSTRATED EMBODIMENTS

[0037] The following includes descriptions of several illustrated embodiments of the present invention, which may share common characteristics and features. It is to be understood that one or more features of any one embodiment may be combinable with one or more features of the other embodiments. In addition, each single feature or combination of features in any of the embodiments may constitute an additional embodiment.

[0038] Embodiments of the invention are directed towards a mouth seal assembly for use with a nasal mask system that eliminates or at least minimizes mouth leak and/or mouth breathing. The mouth seal assembly may be retrofit to an existing nasal mask system, e.g., nasal mask, nozzle assembly, nasal assembly, nasal prongs, nasal pillows, nasal cannulae, nasal inserts, nozzles, etc, or the mouth seal assembly may be provided as original equipment along with a nasal mask system. The mouth seal assembly may or may not include an anti-asphyxia valve. Also, the mouth seal assembly may be supported by a strap arrangement and/or mount that is separate from and/or integrated with the nasal mask system.

[0039] While the mouth seal assembly is described as being used in conjunction with or as part of a nasal mask system, the mouth seal assembly may be adapted for use with other suitable breathing arrangements. That is, the breathing arrangements are merely exemplary, and aspects of the present invention may be applicable to other breathing arrangements, e.g., full-face masks.

1. First Embodiment of Mouth Seal Assembly

[0040] Figs. 1 and 2 illustrate a mouth seal assembly 10 according to an embodiment of the present invention. As illustrated, the mouth seal assembly 10 includes a mouth seal 12 adapted to form a seal with the patient's mouth and a strap arrangement 14 attached to the mouth seal 12 to maintain the mouth seal 12 in a desired position on the patient's face. The mouth seal assembly 10 is intended to be used in conjunction with or as a part of a nasal mask system that provides pressurized breathable gas to the patient's nose, e.g., nasal passages. In use, the mouth seal assembly 10 eliminates or at least minimizes mouth leak in order to enhance the effectiveness of therapy.

[0041] In the illustrated embodiment, the mouth seal 12 includes a flat strip of silicone 16 or similar flexible material. As illustrated, the mouth seal 12 includes a length and height sufficient to completely cover the patient's mouth. A small ridge 18 may be incorporated into the mouth seal 12 to assist location between the patient's lips. The mouth seal 12 is held against the patient's lips by the strap arrangement 14 which includes a strap 20 that extends around the back of the patient's neck. Ends of the strap 20 may be attached to the mouth seal 12 in any suitable manner, e.g., anchors, hook and loop fasteners, etc.

[0042] The mouth seal assembly 10 also includes an anti-asphyxia valve 30 that provides an air passage to the patient in the absence of pressure. The anti-asphyxia valve 30 is provided to the mouth seal 12 over the patient's lips to allow the patient to breathe in freely in the absence of pressure but prevent exhalation.

[0043] In an alternative embodiment, the mouth seal assembly 10 may be used without the anti-asphyxia valve 30. In this embodiment, the patient may open his/her mouth to breath when air pressure is not present, e.g., in the case of a power supply failure. This is possible since a seal is formed by air pressure causing the patient's lips to "bellow". Thus, the seal is only "activated" when air pressure is present.

[0044] The mouth seal assembly 10 differs from a mask in that it is independent from the supply of pressurized air. In use, when the patient has a tendency for mouth leak, the pressure inside the patient's mouth pushes the patient's lips against the mouth seal 12. Thus, the patient's lips conform to the mouth seal 12 due to the differential pressure between the patient's mouth and the outside of the mouth seal 12. This arrangement enables an effective

mouth seal, thereby eliminating or at least minimizing the loss of therapy effectiveness resulting from mouth leak.

[0045] Figs. 3 and 4 illustrate the mouth seal assembly 10 being used in conjunction with a nasal mask system. As illustrated, the nasal mask system includes a nasal mask 50 adapted to form a seal with the patient's nose, e.g., nasal passages. The nasal mask 50 includes a nasal assembly 60 structured to sealingly communicate with nasal passages of the patient's nose in use, and headgear 70 attached to the nasal assembly 60 to maintain the nasal assembly 60 in a desired position on the patient's face.

[0046] The illustrated nasal mask 50 is commercially sold under the name of SWIFT® by ResMed Ltd. Further details and embodiments of this nasal mask 50 are disclosed in U.S. Patent Application Nos. 10/781,929, filed February 20, 2004, and 11/101,657, filed April 8, 2005, the entireties of both being incorporated herein by reference. While the mouth seal assembly 10 is described as being used in conjunction with a nasal mask of the type described above, it may be implemented into other nasal masks. That is, the nasal mask 50 is merely exemplary, and the mouth seal assembly 10 may be used in conjunction with any suitable nasal mask, e.g., nasal assembly, nasal prongs, nasal pillows, nasal cannulae, nasal inserts, nozzles, etc.

[0047] In the illustrated embodiment, the mouth seal assembly 10 includes its own strap arrangement 14 to maintain the mouth seal 12 in a desired position. However, the headgear 70 of the nasal mask 50 may be modified to hold the mouth seal 12 in place. In this arrangement, a separate adjustment may be provided to adjust the position of the mouth seal 12. It is also possible that the mouth seal 12 may be maintained in position without straps. In an alternative embodiment, the mask may be modified to add support to the mouth seal.

2. Second Embodiment of Mouth Seal Assembly

[0048] Figs. 5 and 6 illustrate a mouth seal assembly 210 according to another embodiment of the present invention. As illustrated, the mouth seal assembly 210 includes a mouth seal 212 adapted to form a seal with the patient's mouth and a strap arrangement 214 attached to the mouth seal 212 to maintain the mouth seal 212 in a desired position on the patient's face.

[0049] In the illustrated embodiment, the mouth seal 212 includes an inflated, gel-filled, or foam-filled balloon section 216. As illustrated, the mouth seal 212 includes a length and height sufficient to completely cover the patient's mouth. The mouth seal 212 is held against the patient's lips by the strap arrangement 214 which includes a strap 220 that extends around the back of the patient's neck. Ends of the strap 220 may be attached to the mouth seal 212 in any suitable manner, e.g., anchors, hook and loop fasteners, etc.

[0050] The mouth seal assembly 210 also includes an anti-asphyxia valve 230 that provides an air passage to the patient in the absence of pressure. The anti-asphyxia valve 230 is provided to the mouth seal 212 over the patient's lips to allow the patient to breathe in freely in the absence of pressure but prevent exhalation.

[0051] Similar to the mouth seal assembly 10 described above, the mouth seal assembly 210 is independent from the supply of pressurized air and the patient's lips conform to the mouth seal 212 due to the differential pressure between the patient's mouth and the outside of the mouth seal.

[0052] In an alternative embodiment, the mouth seal assembly 210 may be used without the anti-asphyxia valve 230. In this embodiment, the patient may open his/her mouth to breath when air pressure is not present, e.g., in the case of a power supply failure. This is possible since a seal is formed by air pressure causing the patient's lips to "bellow". Thus, the seal is only "activated" when air pressure is present.

[0053] In an embodiment, the mouth seal assembly 210 may include a small locating ridge such as that described above. In another embodiment, the balloon section 216 may be solid and shaped to fit the patient's lips.

3. Third Embodiment of Mouth Seal Assembly

[0054] Figs. 7-10 illustrate a mouth seal assembly 310 according to another embodiment of the present invention. As illustrated in Figs. 7-8, the mouth seal assembly 310 is used in conjunction with a nasal mask 350 adapted to form a seal with the patient's nose. The nasal mask 350 includes a nasal cushion/frame assembly 360 structured to seal around the patient's nose in use, and headgear 370 attached to the nasal cushion/frame assembly 360 to maintain the nasal cushion/frame assembly 360 in a desired position on the patient's face.

[0055] The illustrated nasal mask 350 is commercially sold under the name of MIRAGE® by ResMed Ltd. Further details and embodiments of this nasal mask 350 are disclosed in U.S. Patent No. 6,112,746, the entirety being incorporated herein by reference. While the mouth seal assembly 310 is described as being used in conjunction with a nasal mask of the type described above, it may be implemented into other nasal masks. That is, the nasal mask 350 is merely exemplary, and the mouth seal assembly 310 may be used in conjunction with any suitable nasal mask, e.g., nasal assembly, nasal prongs, nasal pillows, nasal cannulae, nasal inserts, nozzles, etc.

[0056] The mouth seal assembly 310 includes a mouth seal 312 adapted to form a seal with the patient's mouth and a strap arrangement 314 attached to the mouth seal 312 to maintain the mouth seal 312 in a desired position on the patient's face. In the illustrated embodiment, the mouth seal 312 includes a curved strip of silicone 316 or similar flexible material that generally conforms to the curvature of the patient's mouth region (see Figs. 9 and 10). The mouth seal 312 includes a length and height sufficient to completely cover the patient's mouth.

[0057] The mouth seal assembly 310 also includes an anti-asphyxia valve 330 that provides an air passage to the patient in the absence of pressure. The anti-asphyxia valve 330 is provided to the mouth seal 312 over the patient's lips to allow the patient to breathe in freely in the absence of pressure but prevent exhalation in the presence of air pressure. As shown in Fig. 10, a slit 317 is provided in the silicone 316 to communicate the anti-asphyxia valve 330 with the patient's mouth.

[0058] In an alternative embodiment, the mouth seal assembly 310 may be used without the anti-asphyxia valve 330. In this embodiment, the patient may open his/her mouth to breath when air pressure is not present, e.g., in the case of a power supply failure. This is possible since a seal is formed by air pressure causing the patient's lips to "bellow". Thus, the seal is only "activated" when air pressure is present.

[0059] The mouth seal 312 is held against the patient's lips by the strap arrangement 314 which includes a strap 320 that extends along the sides of the patient's face. At least one end of the strap 320 includes a Velcro® section 322 that allows the end to adjustably attach to a respective lower strap 372 of the nasal mask headgear 370 (see Fig. 8). However, the strap

arrangement 314 may be independent of the nasal mask headgear 370, e.g., extend around the back of the patient's neck.

[0060] In the illustrated embodiment, the strap 320 of the headgear arrangement 314 includes an opening 324 adapted to receive the anti-asphyxia valve 330 therethrough. The anti-asphyxia valve 330 protrudes from the mouth seal 312 and includes a flange 332 that retains the strap 320 to the anti-asphyxia valve 330 and hence the mouth seal 312. However, the mouth seal 312 may be attached to the headgear arrangement 314 in any other suitable manner.

[0061] Similar to the mouth seal assembly 10 described above, the mouth seal assembly 310 is independent from the supply of pressurized air and the patient's lips conform to the mouth seal 312 due to the differential pressure between the patient's mouth and the outside of the mouth seal.

4. Fourth Embodiment of Mouth Seal Assembly

[0062] Fig. 11 illustrates a mouth seal assembly 410 according to another embodiment of the present invention. As illustrated, the mouth seal assembly 410 is used in conjunction with a nasal mask 450 adapted to form a seal with the patient's face. The nasal mask 450 includes a nasal cushion/frame assembly 460 structured to seal around the patient's nose in use, and headgear 470 attached to the nasal cushion/frame assembly 460 to maintain the nasal cushion/frame assembly 460 in a desired position on the patient's face.

[0063] The illustrated nasal mask 450 is commercially sold under the name of ACTIVA® by ResMed Ltd. Further details and embodiments of this nasal mask 450 are disclosed in U.S. Patent Application No. 10/655,622, filed September 5, 2003, the entirety being incorporated herein by reference. While the mouth seal assembly 410 is described as being used in conjunction with a nasal mask of the type described above, it may be implemented into other nasal masks. That is, the nasal mask 450 is merely exemplary, and the mouth seal assembly 410 may be used in conjunction with any suitable nasal mask, e.g., nasal assembly, nasal prongs, nasal pillows, nasal cannulae, nasal inserts, nozzles, etc.

[0064] The mouth seal assembly 410 includes a mouth seal 412 adapted to form a seal with the patient's mouth. In the illustrated embodiment, the mouth seal 412 includes a strip of silicone 416 or similar flexible material that generally conforms to the curvature of the

patient's mouth region. The mouth seal 412 includes a length and height sufficient to completely cover the patient's mouth.

[0065] The mouth seal assembly 410 also includes an anti-asphyxia valve 430 that provides an air passage to the patient in the absence of pressure. The anti-asphyxia valve 430 is provided to the mouth seal 412 over the patient's lips to allow the patient to breathe in freely in the absence of pressure but prevent exhalation in the presence of pressure.

[0066] In an alternative embodiment, the mouth seal assembly 410 may be used without the anti-asphyxia valve 430. In this embodiment, the patient may open his/her mouth to breath when air pressure is not present, e.g., in the case of a power supply failure. This is possible since a seal is formed by air pressure causing the patient's lips to "bellow". Thus, the seal is only "activated" when air pressure is present.

[0067] In the illustrated embodiment, the mouth seal assembly 410 is attached to the nasal mask 450. In addition, the headgear 470 of the nasal mask 450 is attached to the mouth seal assembly 410 to hold the mouth seal 412 against the patient's lips as well as hold a lower portion of the nasal cushion/frame assembly 460 against the patient's nasal region.

[0068] Specifically, a support structure 480 is provided to attach the mouth seal assembly 410 to the nasal mask 450. In the illustrated embodiment, the support structure 480 includes an anchor 482 attached to the nasal cushion/frame assembly 460 and a wire arrangement 484 that wraps around the anti-asphyxia valve 430 to connect the mouth seal assembly 410 to the anchor 482. However, the mouth seal assembly 410 may be attached to the nasal mask 450 in other suitable manners.

[0069] The headgear 470 of the nasal mask 450 includes upper straps 472 attached to a forehead support 452 of the nasal mask 450 and lower straps 474 that are removably attached to the mouth seal assembly 410. As illustrated, the end of each lower strap 474 includes a clip 476 that is adapted to engage a respective clip receiver 490 provided to the mouth seal assembly 410. The clip receivers 490 are attached to the mouth seal assembly by a wire arrangement 492 that wraps around the wire arrangement 484 associated with the nasal mask 450. However, the clip receivers 490 may be attached to the mask seal assembly 410 in other suitable manners. In addition, the lower straps 474 may be attached to the mask seal assembly 410 in other suitable manners.

[0070] In use, the upper and lower straps 472, 474 maintain the nasal mask 450 and the mouth seal 412 in a desired position on the patient's face. In another embodiment, the mouth seal assembly 410 may be independent from the nasal mask 450 and a separate strap arrangement may be provided to secure the mouth seal assembly 410 to the patient's head. In this arrangement, clips may be provided to the lower straps 474 that are adapted to engage respective clip receivers 454 provided to the nasal cushion/frame assembly 460.

[0071] Similar to the mouth seal assembly 10 described above, the mouth seal assembly 410 is independent from the supply of pressurized air and the patient's lips conform to the mouth seal 412 due to the differential pressure between the patient's mouth and the outside of the mouth seal.

5. Fifth Embodiment of Mouth Seal Assembly

[0072] Figs. 12-14 illustrate a mouth seal assembly 510 according to another embodiment of the present invention. As illustrated, the mouth seal assembly 510 is used in conjunction with an ACTIVA® nasal mask 450. The ACTIVA® nasal mask 450 is indicated with similar reference numerals as described above. While the mouth seal assembly 510 is described as being used in conjunction with a nasal mask of the type described above, it may be implemented into other nasal masks. That is, the nasal mask 450 is merely exemplary, and the mouth seal assembly 510 may be used in conjunction with any suitable nasal mask, e.g., nasal assembly, nasal prongs, nasal pillows, nasal cannulae, nasal inserts, nozzles, etc.

[0073] The mouth seal assembly 510 includes a mouth seal 512 adapted to form a seal with the patient's mouth. In the illustrated embodiment, the mouth seal 512 includes a curved strip of silicone 516 or similar flexible material that generally conforms to the curvature of the patient's mouth region. The mouth seal 512 includes a length and height sufficient to completely cover the patient's mouth.

[0074] The mouth seal assembly 510 also includes an anti-asphyxia valve 530 that provides an air passage to the patient in the absence of pressure. The anti-asphyxia valve 530 is provided to the mouth seal 512 over the patient's lips to allow the patient to breathe in freely in the absence of pressure but prevent exhalation in the presence of pressure. As shown in Fig. 14, a slit 517 is provided in the silicone 516 to communicate the anti-asphyxia valve 530 with the patient's mouth.

[0075] In an alternative embodiment, the mouth seal assembly 510 may be used without the anti-asphyxia valve 530. In this embodiment, the patient may open his/her mouth to breath when air pressure is not present, e.g., in the case of a power supply failure. This is possible since a seal is formed by air pressure causing the patient's lips to "bellow". Thus, the seal is only "activated" when air pressure is present.

[0076] In the illustrated embodiment, the mouth seal assembly 510 is attached to the nasal mask 450. In addition, the headgear 470 of the nasal mask 450 is adapted to hold the mouth seal 512 against the patient's lips as well as hold a lower portion of the nasal cushion/frame assembly 460 against the patient's nasal region.

[0077] Specifically, a support structure 580 is provided to attach the mouth seal assembly 510 to the nasal mask 450. In the illustrated embodiment, the support structure 580 includes an anchor 582 attached to the nasal cushion/frame assembly 460 and a wire arrangement 584 that wraps around the anti-asphyxia valve 530 to connect the mouth seal assembly 510 to the anchor 582. However, the mouth seal assembly 510 may be attached to the nasal mask 450 in other suitable manners.

[0078] The headgear 470 of the nasal mask 450 includes upper straps 472 attached to a forehead support 452 of the nasal mask 450 and lower straps 474 attached to a lower portion of the nasal cushion/frame assembly 460. Specifically, the end of each lower strap 474 includes a clip 477 that is adapted to be engaged within a respective clip receiver 454 provided to the nasal cushion/frame assembly 460. In use, the upper and lower straps 472, 474 maintain the nasal mask 450 and the mouth seal 512 in a desired position on the patient's face. In another embodiment, the mouth seal assembly 510 may be independent from the nasal mask 450 and a separate strap arrangement may be provided to secure the mouth seal assembly 510 to the patient's head.

[0079] Similar to the mouth seal assembly 10 described above, the mouth seal assembly 510 is independent from the supply of pressurized air and the patient's lips conform to the mouth seal 512 due to the differential pressure between the patient's mouth and the outside of the mouth seal.

6. Sixth Embodiment of Mouth Seal Assembly

[0080] Figs. 15 and 16 illustrate a mouth seal assembly 610 according to another embodiment of the present invention. As illustrated, the mouth seal assembly 610 is used in conjunction with an MIRAGE® nasal mask 350. The MIRAGE® nasal mask 350 is indicated with similar reference numerals as described above. While the mouth seal assembly 610 is described as being used in conjunction with a nasal mask of the type described above, it may be implemented into other nasal masks. That is, the nasal mask 350 is merely exemplary, and the mouth seal assembly 610 may be used in conjunction with any suitable nasal mask, e.g., nasal assembly, nasal prongs, nasal pillows, nasal cannulae, nasal inserts, nozzles, etc.

[0081] The mouth seal assembly 610 includes a mouth seal 612 adapted to form a seal with the patient's mouth and a strap arrangement 614 attached to the mouth seal 612 to maintain the mouth seal 612 in a desired position on the patient's face. In the illustrated embodiment, the mouth seal 612 includes an elongated substantially rigid tube 616 that sits on the patient's lips. The tube 616 may have a solid or hollow configuration, and includes a length sufficient to extend along the patient's lips.

[0082] The tube 616 is held against the patient's lips by the strap arrangement 614 which includes side straps 620 that extend along the sides of the patient's face. One end of each strap 620 is attached to a respective end of the tube 616, e.g., by hook mechanism, and the opposing end of each strap 620 is attached to a respective lower strap 372 of the nasal mask headgear 370, e.g., by a clip mechanism, hook and loop fasteners, etc. However, the strap arrangement 614 may be independent of the nasal mask headgear 370, e.g., extend around the back of the patient's neck.

[0083] The tube 616 is independent from the supply of pressurized air. The tube 616 provides a surface upon which the patient's lips are pushed due to mouth leak and thus form a seal. This mechanism provides a seal that is "activated" when pressure is applied to the mask, however in the event of power failure or lack or pressure, the seal is not "activated" and thus the patient can open his/her mouth to breath.

7. Seventh Embodiment of Mouth Seal Assembly

[0084] Figs. 17 to 20 illustrate a mouth seal assembly 710 according to another embodiment of the present invention. As illustrated, the mouth seal assembly 710 is used in conjunction with a SWIFT® nasal mask 50. The SWIFT® nasal mask 50 is indicated with similar reference numerals as described above. While the mouth seal assembly 710 is described as being used in conjunction with a nasal mask of the type described above, it may be implemented into other nasal masks. That is, the nasal mask 50 is merely exemplary, and the mouth seal assembly 710 may be used in conjunction with any suitable nasal mask.

[0085] The mouth seal assembly 710 includes a mouth seal 712 adapted to form a seal with the patient's mouth. In the illustrated embodiment, the mouth seal 712 includes a curved strip of silicone 716 or similar flexible material that generally conforms to the curvature of the patient's mouth region (e.g., see Fig. 17). The mouth seal 712 includes a length and height sufficient to completely cover the patient's mouth. Figs. 19 and 20 illustrate transparent and solid views of the mouth seal 712 to show the mouth seal 712 in relation to the patient's mouth.

[0086] In the illustrated embodiment, the mouth seal 712 is maintained in a desired position by the headgear 70 and/or the nasal assembly 60 of the nasal mask 50. The headgear 70 and/or nasal assembly 60 may be modified to support the mouth seal 712 in place. Thus, the mouth seal 712 is maintained in position without its own strap arrangement. However, the mouth seal 712 may be supported in other suitable manners.

[0087] Similar to the mouth seal assembly 10 described above, the mouth seal assembly 710 is independent from the supply of pressurized air and the patient's lips conform to the mouth seal 712 due to the differential pressure between the patient's mouth and the outside of the mouth seal. The mouth seal 712 may be provided with or without an anti-asphyxia valve.

8. Eighth Embodiment of Mouth Seal Assembly

[0088] Figs. 21 to 23 illustrate a mouth seal assembly 810 according to another embodiment of the present invention. As illustrated, the mouth seal assembly 810 is used in conjunction with an ACTIVA® nasal mask 450. The ACTIVA® nasal mask 450 is indicated with similar reference numerals as described above. While the mouth seal assembly 810 is

described as being used in conjunction with a nasal mask of the type described above, it may be implemented into other nasal masks. That is, the nasal mask 450 is merely exemplary, and the mouth seal assembly 810 may be used in conjunction with any suitable nasal mask, e.g., nasal assembly, nasal prongs, nasal pillows, nasal cannulae, nasal inserts, nozzles, etc.

[0089] The mouth seal assembly 810 includes a mouth seal 812 adapted to form a seal with the patient's mouth and a support structure or mount 880 to support the mouth seal 812 on the nasal mask 450. In the illustrated embodiment, the mouth seal 812 is formed with foam, e.g., foam-filled cylinder or strip, and provides a foam seal or interface with the patient's mouth. The foam mouth seal 812 includes a length and height sufficient to completely cover the patient's mouth. In an alternative embodiment, the foam mouth seal 812 may be shaped to better fit the facial profile around the patient's lips, e.g., see Fig. 25 described below.

[0090] The foam mouth seal 812 provides a compliant seal that comfortably engages the patient's mouth. The compliant nature of the foam ensures that it deforms to seal against a range of facial profiles. That is, the foam can deform to the appropriate size and shape without compromising the seal and without adding discomfort to the patient.

[0091] When the nasal mask 450 is pressurized, the patients lips will "bellow" to engage the foam mouth seal 812 and form a seal that substantially prevents mouth leak and mouth breathing. If the nasal mask 450 is not pressurized, e.g., in the case of a power supply failure, the foam mouth seal 812 is not "activated" and the patient is free to open his/her mouth to breathe. In an alternative embodiment, an anti-asphyxia valve may be provided to the mouth seal or the air supply to the mask. Also, the mouth seal 812 may alternatively be filled with gel, silicone, or air to provide a similar compliant seal.

[0092] The support structure or mount 880 is preferably lightweight and may be constructed of a polycarbonate or steel material, for example. The support structure 880 may be mounted to the nasal mask and mouth seal 812 in any suitable manner. In an embodiment, the support structure 880 may be biased, e.g., spring biased, to provide the mouth seal 812 with a sealing force onto the patient's mouth. However, the mouth seal 812 may be attached to the nasal mask 450 in other suitable manners. For example, existing structures on the nasal mask may be used to support the mouth seal. In an embodiment, the mount may be supported by one or more ports typically provided on nasal masks (and typically closed by a ports cap).

In another embodiment, the mount may be supported by headgear clips associated with the nasal mask headgear. The headgear clip may be modified to incorporate the mount.

[0093] Similar to the mouth seal assembly 10 described above, the mouth seal assembly 810 is independent from the supply of pressurized air and the patient's lips conform to the mouth seal 812 due to the differential pressure between the patient's mouth and the outside of the mouth seal.

9. Ninth Embodiment of Mouth Seal Assembly

[0094] Fig. 24 illustrates a mouth seal assembly 910 according to another embodiment of the present invention. As illustrated, the mouth seal assembly 910 is used in conjunction with an ACTIVA® nasal mask 450. The ACTIVA® nasal mask 450 is indicated with similar reference numerals as described above. While the mouth seal assembly 910 is described as being used in conjunction with a nasal mask of the type described above, it may be implemented into other nasal masks. That is, the nasal mask 450 is merely exemplary, and the mouth seal assembly 910 may be used in conjunction with any suitable nasal mask, e.g., nasal assembly, nasal prongs, nasal pillows, nasal cannulae, nasal inserts, nozzles, etc.

[0095] The mouth seal assembly 910 includes a mouth seal 912 adapted to form a seal with the patient's mouth and a support structure or mount 980 to support the mouth seal 912 on the nasal mask 450. In the illustrated embodiment, the mouth seal 912 is formed with foam, e.g., foam-filled cylinder or strip, and provides a foam seal or interface with the patient's mouth. Similar to mouth seal 812 described above, the foam mouth seal 912 provides a compliant seal that comfortably engages the patient's mouth. In alternative embodiments, the mouth seal 912 may be filled with gel, silicone, or air to provide a similar compliant seal.

[0096] As shown in Fig. 25, the foam mouth seal 912 may be shaped to better fit the facial profile around the patient's lips. In use, the patient's lips would fit within the space 913 provided between upper and lower protrusions 916, 918 of the foam mouth seal 912. In alternative embodiments, either the seal 912 or the mount 980 may be constructed from a malleable material (e.g., spring steel) and formed to best fit the individual patient.

[0097] The support structure or mount 980 is preferably lightweight and may be constructed of a polycarbonate or steel material, for example. The support structure 980 may

be mounted to the nasal mask and mouth seal 912 in any suitable manner. In an embodiment, the support structure 980 may be biased, e.g., constructed of spring steel with a spring bias, to provide the mouth seal 912 with a sealing force onto the patient's mouth. However, the mouth seal 912 may be attached to the nasal mask 450 in other suitable manners.

[0098] Similar to the mouth seal assembly 10 described above, the mouth seal assembly 910 is independent from the supply of pressurized air and the patient's lips conform to the mouth seal 912 due to the differential pressure between the patient's mouth and the outside of the mouth seal. The mouth seal 912 may be provided with or without an anti-asphyxia valve.

10. Alternative Embodiments of Mouth Seal

[0099] Figs. 26-30 illustrate mouth seals according to alternative embodiments of the present invention. Each mouth seal may be used in conjunction with a nasal mask such as the SWIFT®, MIRAGE®, and ACTIVA® nasal masks 50, 350, 450 described above.

[00100] Fig. 26 illustrates a mouth seal 1012 formed with foam, e.g., foam-filled cylinder or strip, that provides a foam seal or interface with the patient's mouth. A mount 1080 is provided to the mouth seal 1012 to support the mouth seal 1012 on a nasal mask. The foam mouth seal 1012 is similar to the foam mouth seals 812, 912 described above.

[00101] Fig. 27 illustrates a mouth seal 1112 formed with foam, e.g., foam-filled cylinder or strip, that provides a foam seal or interface with the patient's mouth. A mount 1180 is provided to the mouth seal 1112 to support the mouth seal 1112 on a nasal mask. As illustrated, the mouth seal 1112 is shaped to fit the facial contours or profile of the patient's face.

[00102] Fig. 28 illustrates a mouth seal 1212 formed with foam, e.g., foam-filled cylinder or strip, that provides a foam seal or interface with the patient's mouth. A mount 1280 is provided to the mouth seal 1212 to support the mouth seal 1212 on a nasal mask. As illustrated, a spring arrangement 1290, e.g., a plurality of coil springs 1292, is provided between the mount 1280 and the mouth seal 1212 to provide the mouth seal 1212 with a sealing force onto the patient's mouth. The sealing force provided by the spring arrangement 1290 will be opposed to the force of the air within the patient's mouth pressing against the lips.

[00103] However, the sealing force may be generated by other suitable arrangements. For example, Fig. 29 illustrates a mouth seal 1312 including a spring, concertina or bellows arrangement. A mount 1380 is provided to the mouth seal 1312 to support the mouth seal 1312 on a nasal mask. The plurality of bellows 1313 of the mouth seal 1312 provide the mouth seal 1312 with a sealing force onto the patient's mouth.

[00104] Fig. 30 illustrates a mouth seal 1412 including a gusset arrangement. A mount 1480 is provided to the mouth seal 1412 to support the mouth seal 1412 on a nasal mask. In use, pressurized air from the nasal mask is provided to the gusseted mouth seal 1412, e.g., via the mount 1480, to expand the gusseted mouth seal 1412 and provide a sealing force onto the patient's mouth.

[00105] In each of the above-described embodiments, the mouth sealing assembly 10, 210, 310, 410, 510, 610, 710, 810, 910 may be used as an optional component of a nasal mask system. That is, the mouth sealing assembly may be optionally used in conjunction with a nasal mask system to eliminate or at least minimize mouth leak in order to enhance the effectiveness of therapy.

[00106] While the invention has been described in connection with what are presently considered to be the most practical and preferred embodiments, it is to be understood that the invention is not to be limited to the disclosed embodiments, but on the contrary, is intended to cover various modifications and equivalent arrangements included within the spirit and scope of the invention. Also, the various embodiments described above may be implemented in conjunction with other embodiments, e.g., aspects of one embodiment may be combined with aspects of another embodiment to realize yet other embodiments. In addition, while the invention has particular application to patients who suffer from OSA, it is to be appreciated that patients who suffer from other illnesses (e.g., congestive heart failure, diabetes, morbid obesity, stroke, barriatric surgery, etc.) can derive benefit from the above teachings. Moreover, the above teachings have applicability with patients and non-patients alike in non-medical applications.

WHAT IS CLAIMED IS:

1. A mouth seal assembly for use with a nasal mask system, comprising:

a mouth seal adapted to form a seal with the patient's mouth, the mouth seal being substantially independent from a supply of pressurized air from the nasal mask system; and

an anti-asphyxia valve provided to the mouth seal over the patient's lips.

2. The mouth seal assembly according to claim 1, wherein the mouth seal includes a substantially flat strip of silicone material.

3. The mouth seal assembly according to claim 1, wherein the mouth seal includes an inflated, gel-filled, or foam-filled balloon section.

4. The mouth seal assembly according to any one of claims 1-3, wherein the mouth seal includes a ridge to locate the mouth seal between the patient's lips.

5. The mouth seal assembly according to any one of claims 1-4, further comprising a strap arrangement to support the mouth seal in a desired position on the patient's face in use.

6. A nasal mask system comprising:

a nasal mask structured to form a seal with the patient's nose and deliver a supply of pressurized air; and

a mouth seal assembly according to any one of claims 1-5.

7. The nasal mask system according to claim 6, wherein the mouth seal assembly includes a strap arrangement to support the mouth seal, the strap arrangement being independent from headgear of the nasal mask, and the strap arrangement including a strap that extends around the back of the patient's neck.

8. The nasal mask system according to claim 6, wherein the mouth seal assembly includes a strap arrangement to support the mouth seal, the strap arrangement including a strap that extends along the sides of the patient's face, each end of the strap being provided to a respective strap of headgear of the nasal mask.

9. The nasal mask system according to claim 8, wherein each end of the strap includes a Velcro® section that allows each end to adjustably attach to the respective strap of the headgear.

10. The nasal mask system according to any one of claims 8-9, wherein the strap is retained to the anti-asphyxia valve.

11. The nasal mask system according to claim 6, wherein the mouth seal assembly is supported by the nasal mask by a support structure.

12. The nasal mask system according to claim 11, wherein the support structure includes an anchor provided to the nasal mask and a wire arrangement that interconnects the anchor and the mouth seal assembly.

13. The nasal mask system according to claim 12, wherein the wire arrangement wraps around the anti-asphyxia valve.

14. The nasal mask system according to any one of claims 6 and 11-13, wherein the nasal mask includes headgear, the headgear including upper straps to support the nasal mask and lower straps to support the mouth seal assembly.

15. The nasal mask system according to claim 14, wherein each lower strap includes a clip that is adapted to engage a respective clip receiver provided to the mouth seal assembly.

16. The nasal mask system according to any one of claims 6 and 11-13, wherein the nasal mask includes headgear attached thereto, the headgear adapted to maintain both the nasal mask and the mouth seal assembly in a desired position on the patient's face.

17. A mouth seal assembly for use with a nasal mask system, comprising:

a substantially rigid tube adapted to form a seal with the patient's lips, the tube being substantially independent from a supply of pressurized air from the nasal mask system; and

a strap arrangement to support the tube in a desired position on the patient's face in use.

18. The mouth seal assembly according to claim 17, wherein the strap arrangement includes side straps that extend along the sides of the patient's face, each strap including an end provided to a respective lower strap of headgear of the nasal mask system.

19. The mouth seal assembly according to any one of claims 17-18, wherein the tube is solid or hollow.

20. A nasal mask system comprising:

a nasal mask structured to form a seal with the patient's nose and deliver a supply of pressurized air; and

a mouth seal assembly according to any one of claims 17-19.

21. A mouth seal assembly for use with a nasal mask system, comprising:

a mouth seal adapted to form a seal with the patient's mouth, the mouth seal being substantially independent from a supply of pressurized air from the nasal mask system; and

a mount provided to the mouth seal and adapted to support the mouth seal on the nasal mask system,

wherein the mouth seal is formed with foam to provide a foam seal or interface with the patient's mouth in use.

22. The mouth seal assembly according to claim 21, wherein foam mouth seal includes a foam-filled cylinder or strip.

23. The mouth seal assembly according to any one of claims 21-22, further comprising an anti-asphyxia valve provided to the mouth seal over the patient's lips.

24. The mouth seal assembly according to any one of claims 21-23, wherein the mount is biased to provided the mouth seal with a sealing force onto the patient's mouth.

25. The mouth seal assembly according to claim 24, further comprising a spring arrangement between the mount and the mouth seal to provide the mouth seal with the sealing force.

26. The mouth seal assembly according to any one of claims 21-25, wherein the mouth seal is shaped or contoured to fit a facial profile around the patient's lips.

27. The mouth seal assembly according to claim 26, wherein the mouth seal includes upper and lower protrusions that define a space adapted to fit the patient's lips in use.

28. A nasal mask system comprising:

a nasal mask structured to form a seal with the patient's nose and deliver a supply of pressurized air; and

a mouth seal assembly according to any one of claims 21-27.

29. A nasal mask system comprising:

a nasal mask structured to form a seal with the patient's nose and deliver a supply of pressurized air; and

a mouth seal assembly provided to the nasal mask, the mouth seal assembly including a mouth seal adapted to form a seal with the patient's mouth and a mount adapted to support the mouth seal on the nasal mask,

wherein the mouth seal includes a spring, bellows or gusset arrangement that provides the mouth seal with a sealing force onto the patient's mouth in use.

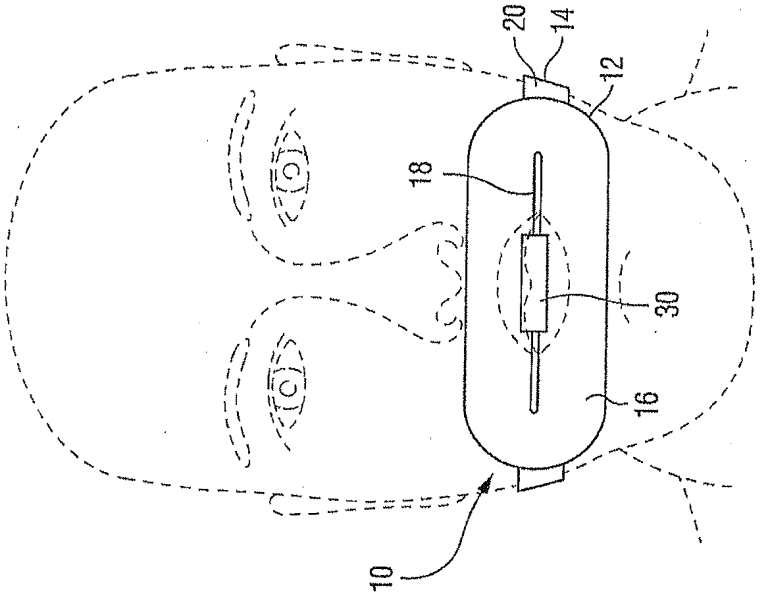

Fig. 2

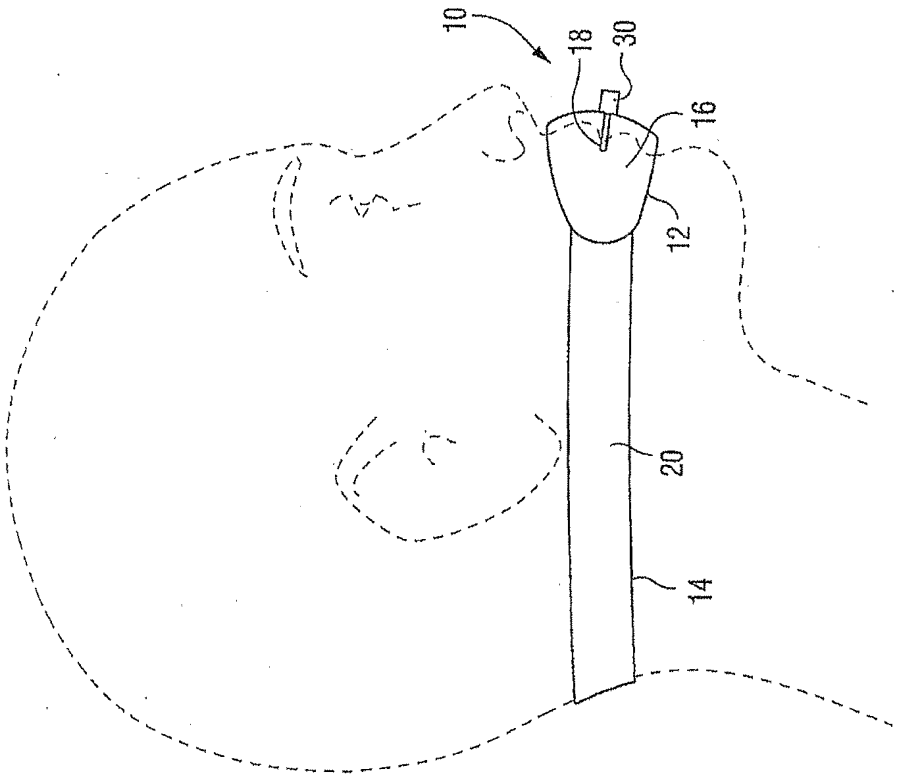

Fig. 1

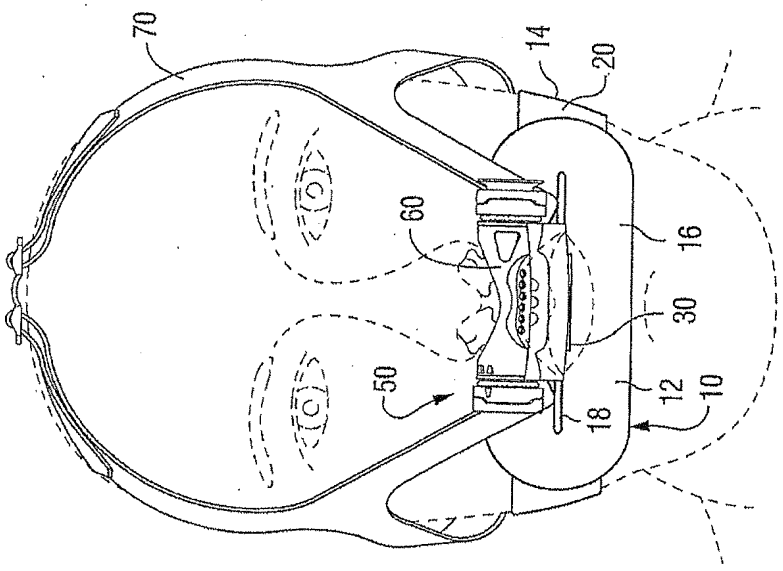

Fig. 4

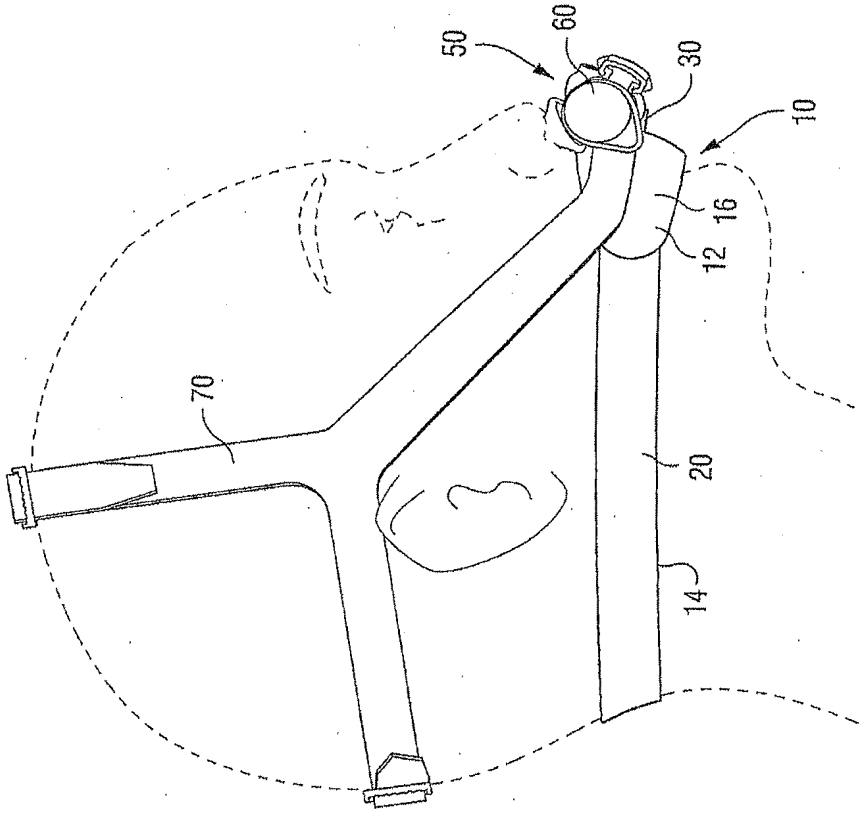

Fig. 3

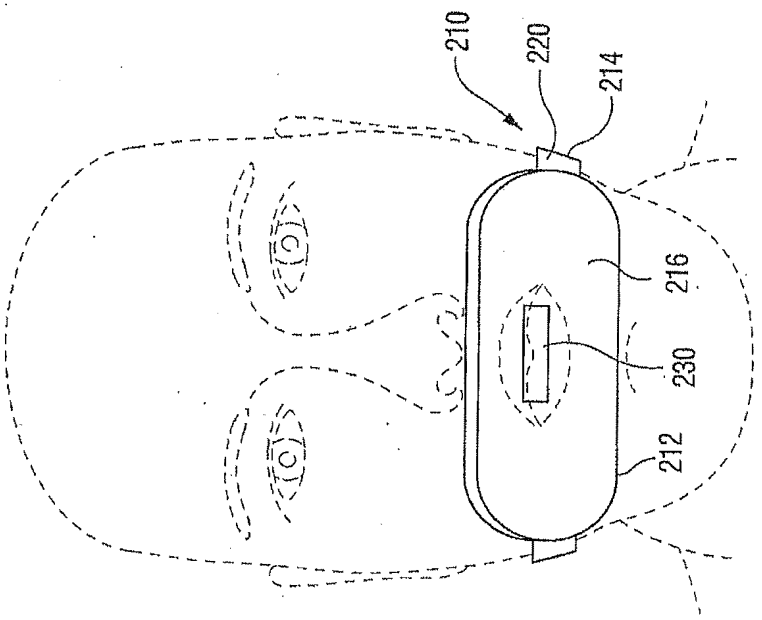

Fig. 6

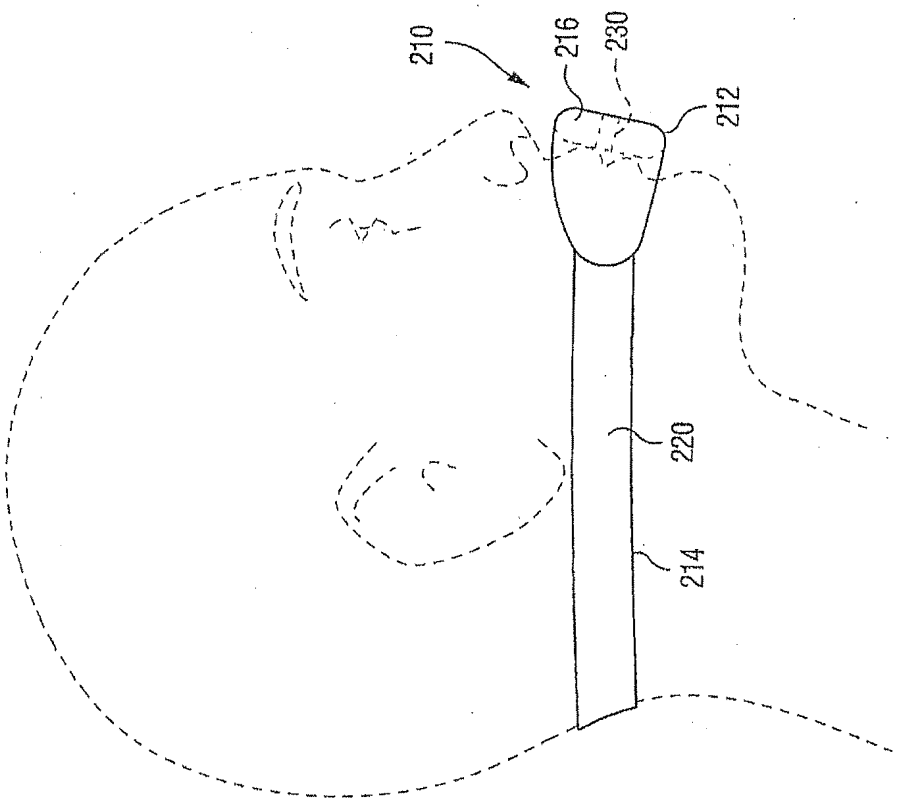

Fig. 5

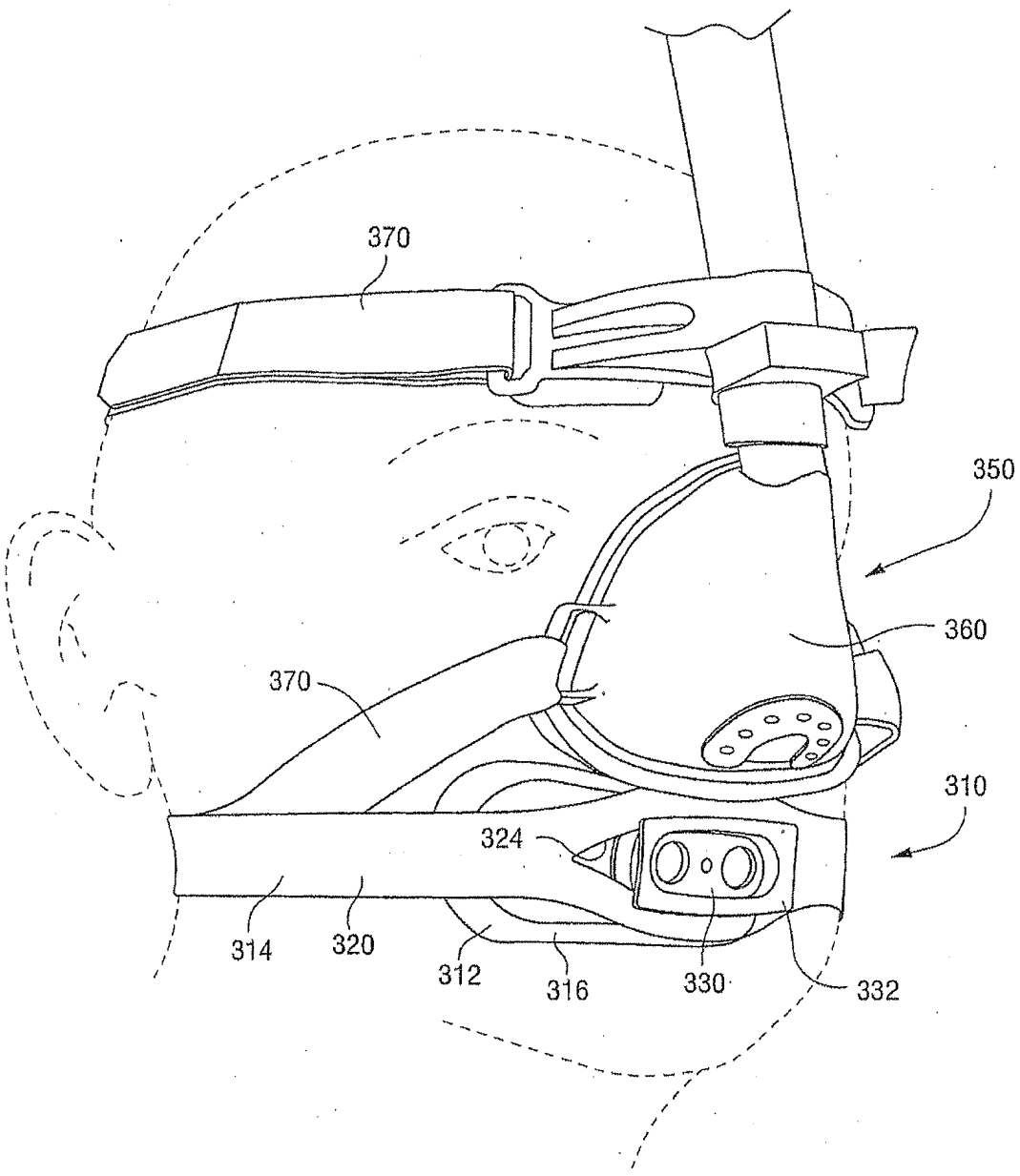

Fig. 7

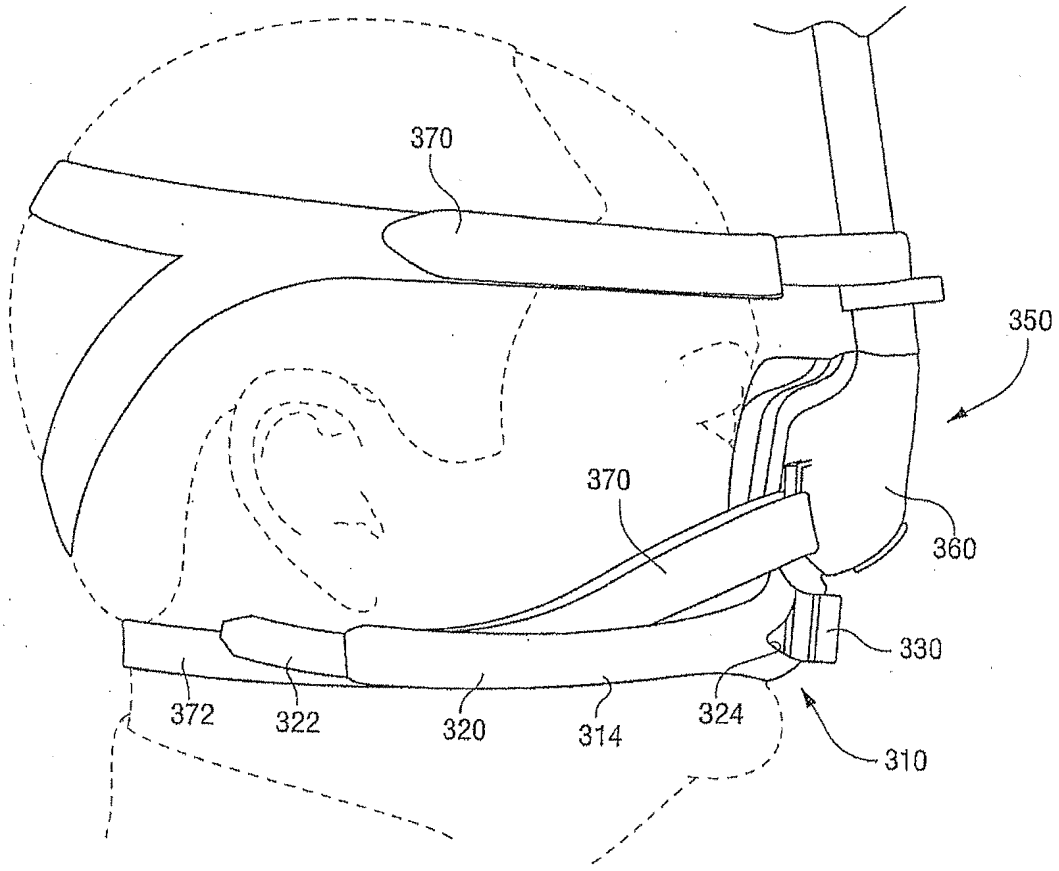

Fig. 8

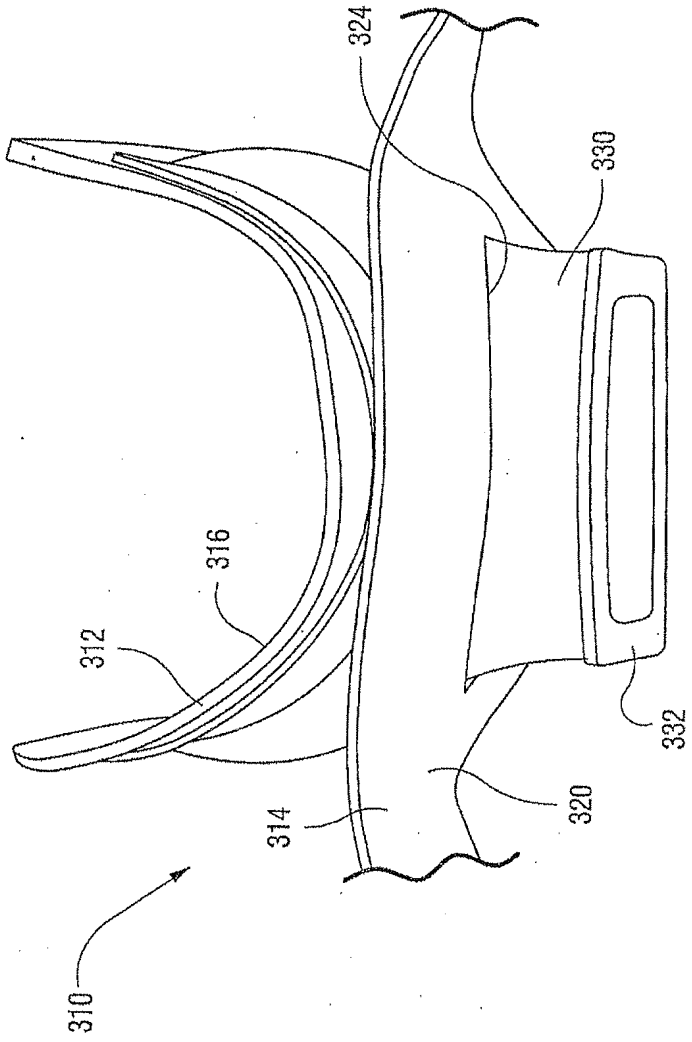

Fig. 9

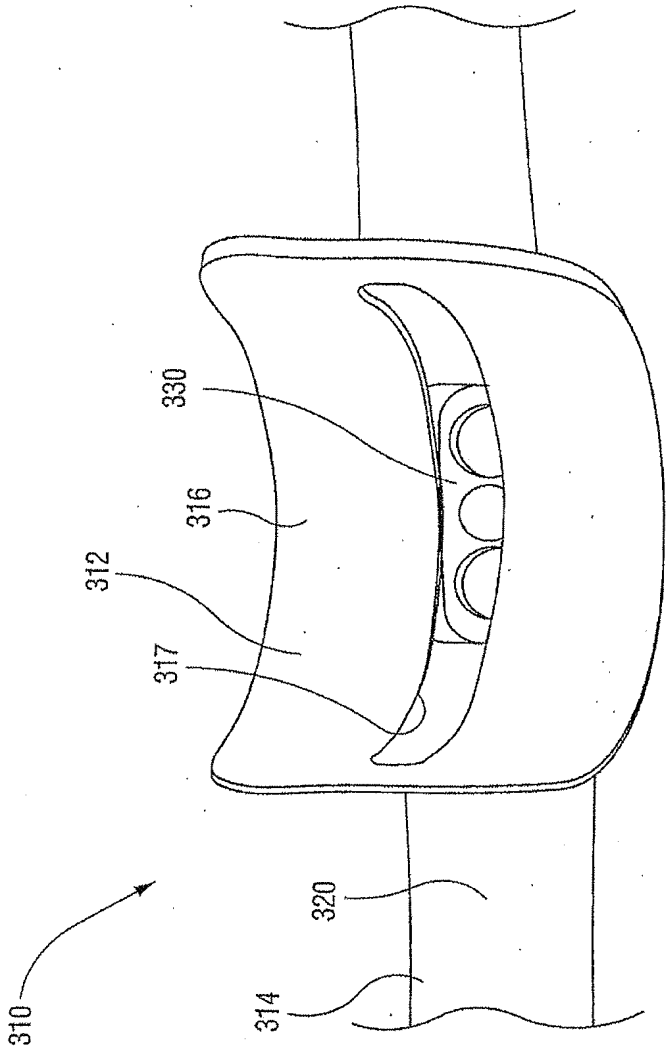

Fig. 10

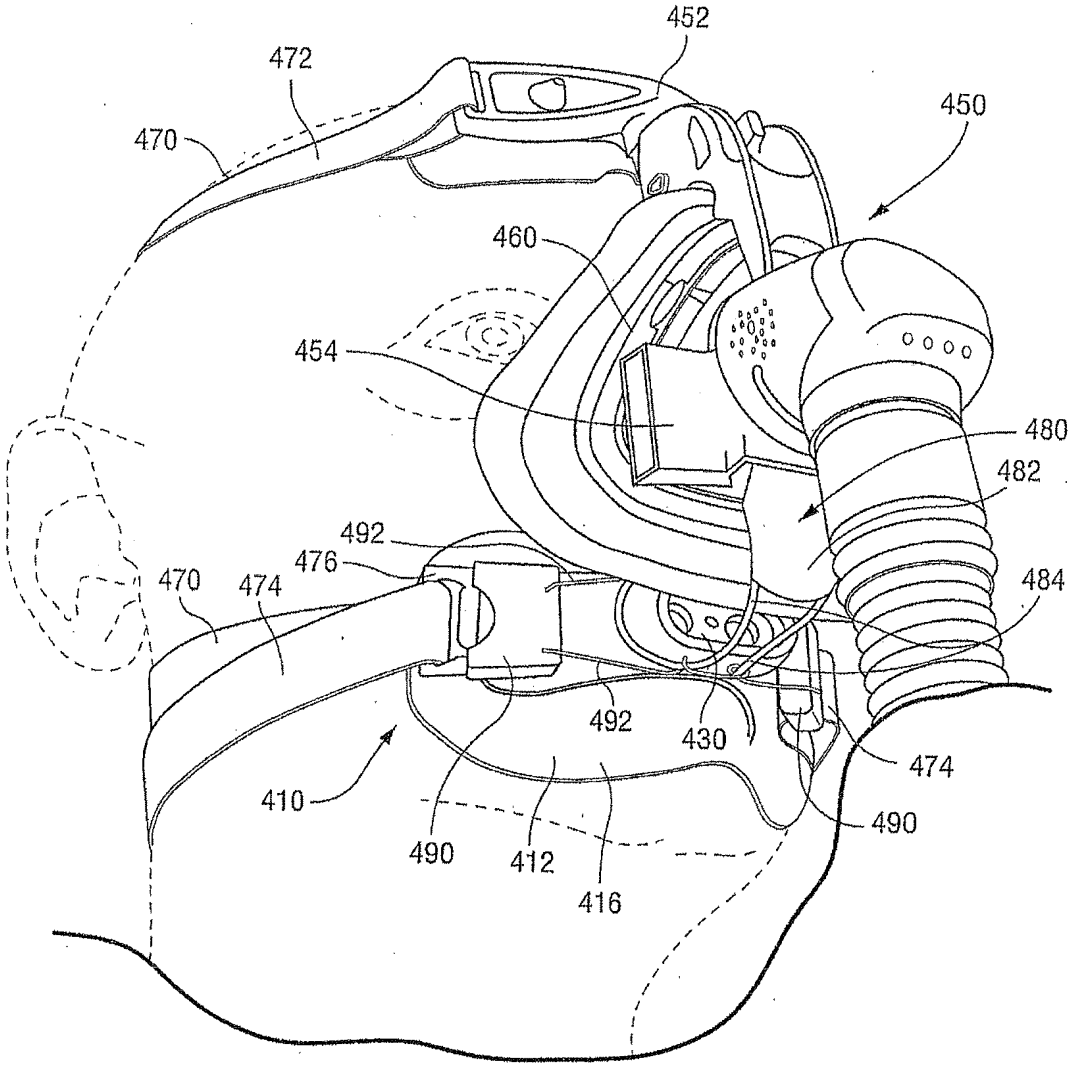
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Fig. 11

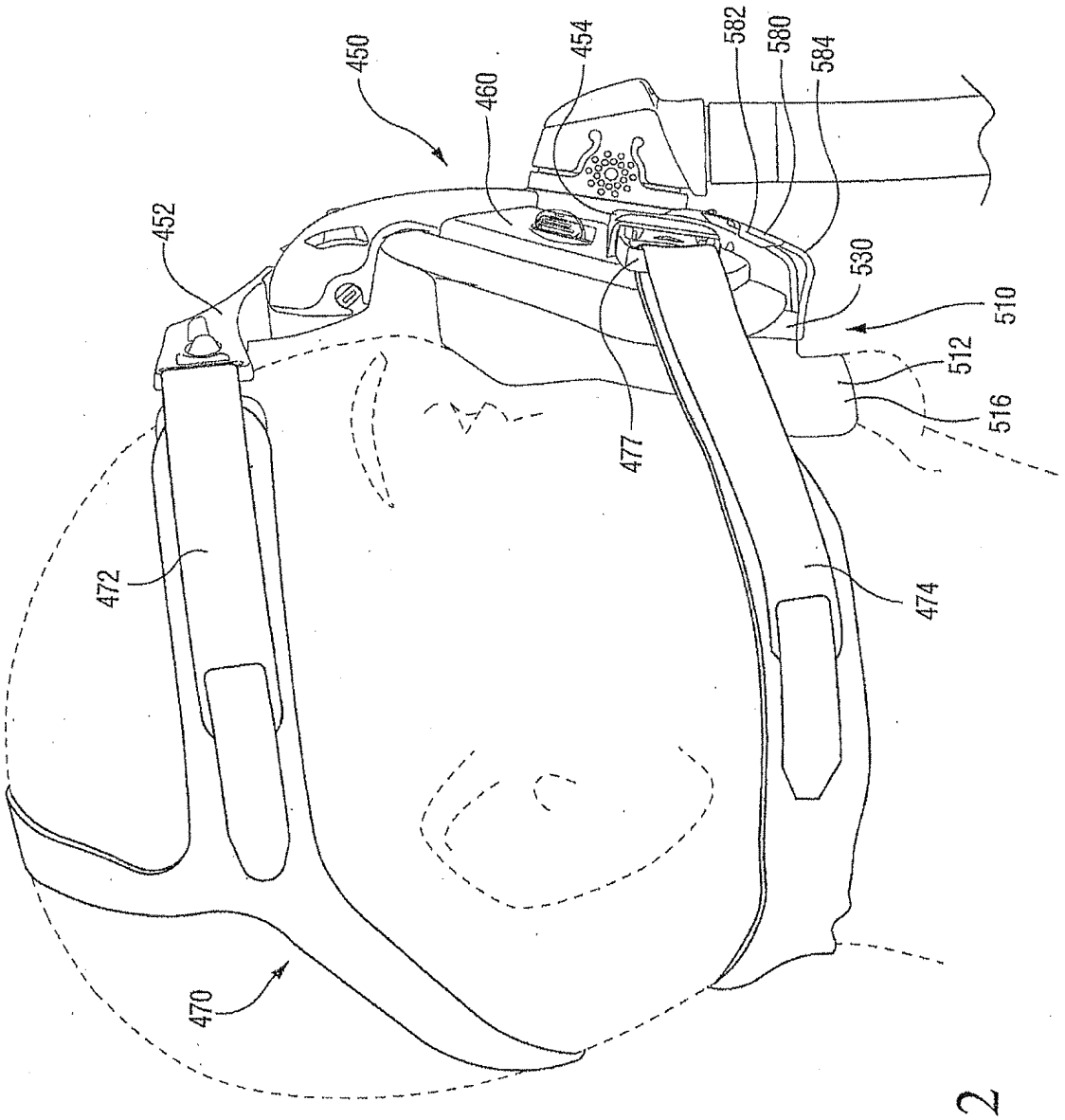


Fig. 12

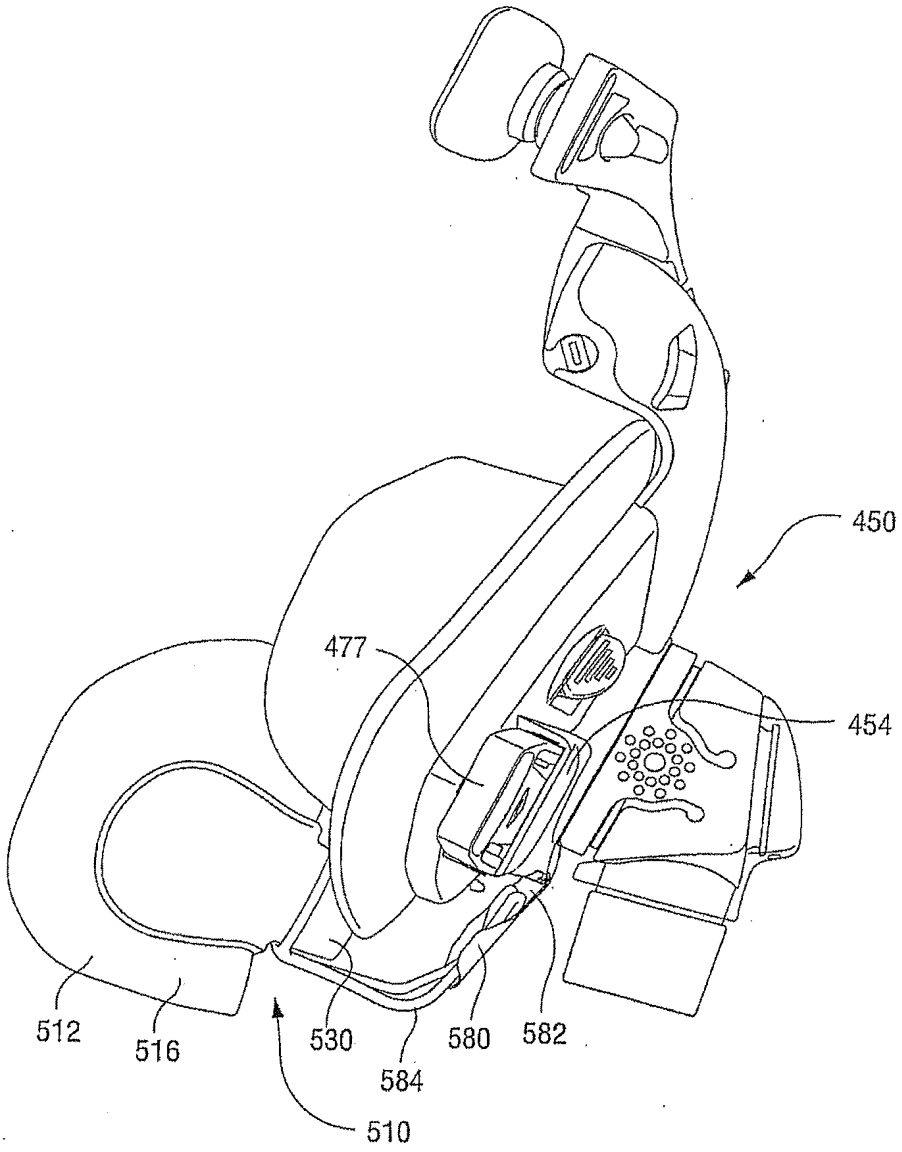


Fig. 13

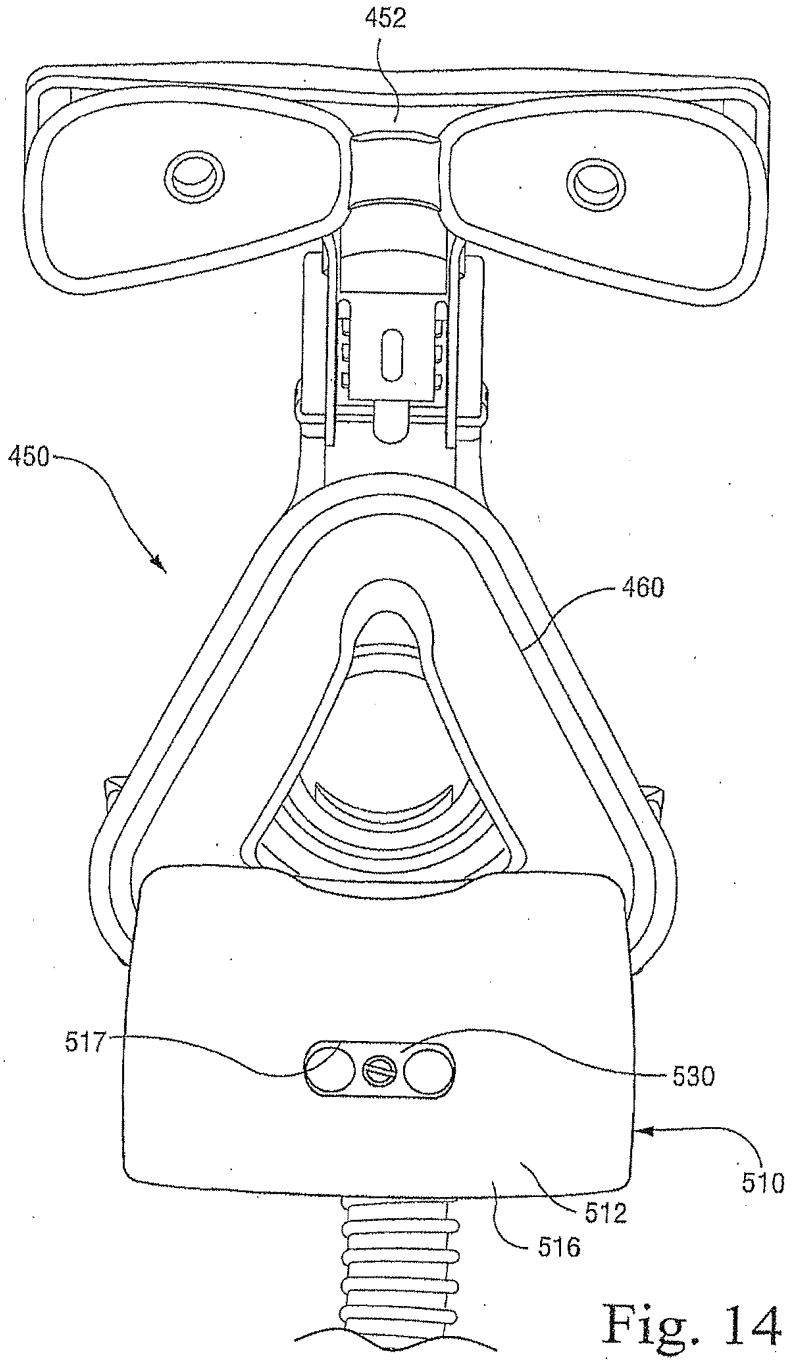


Fig. 14

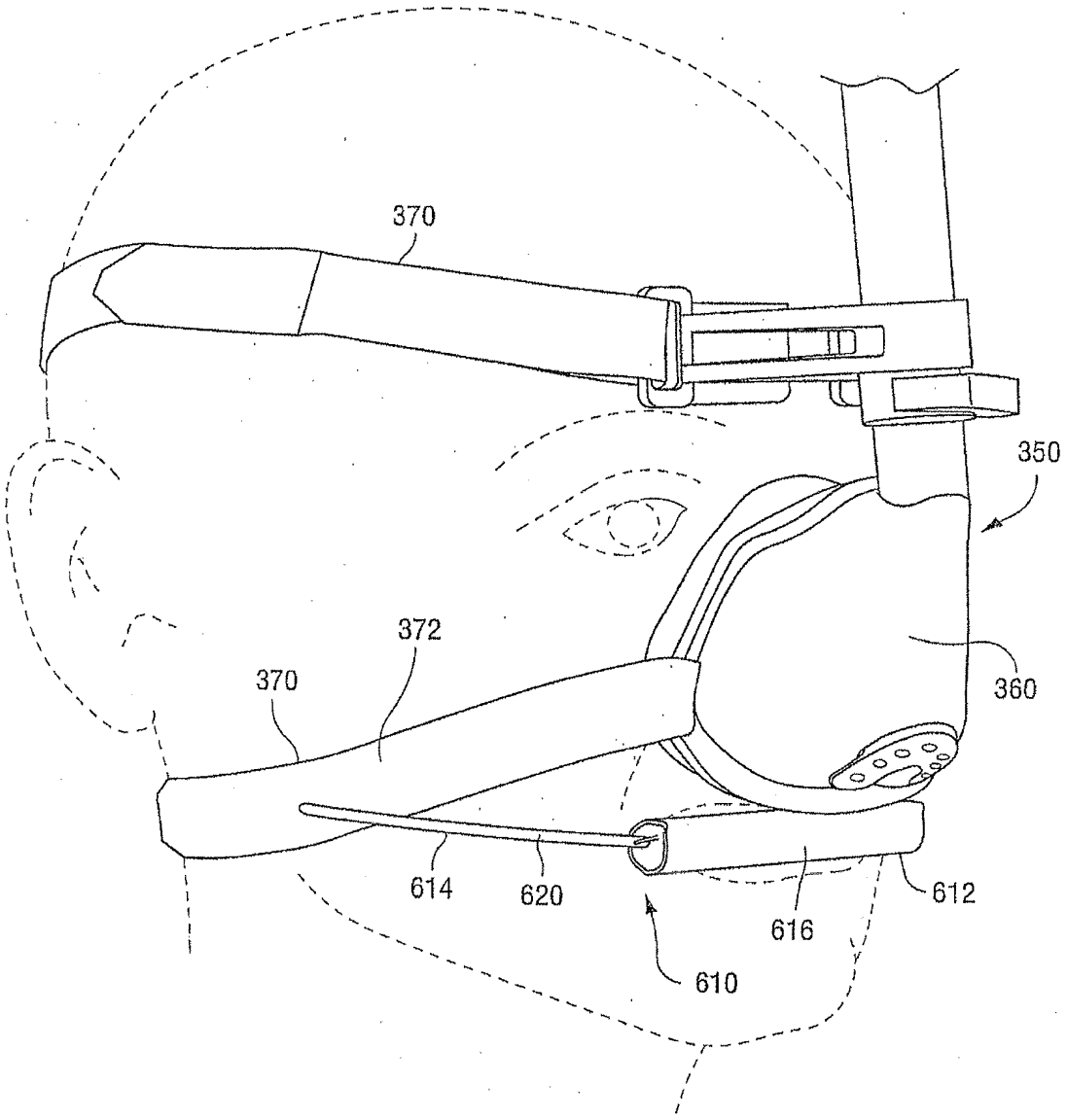


Fig. 15

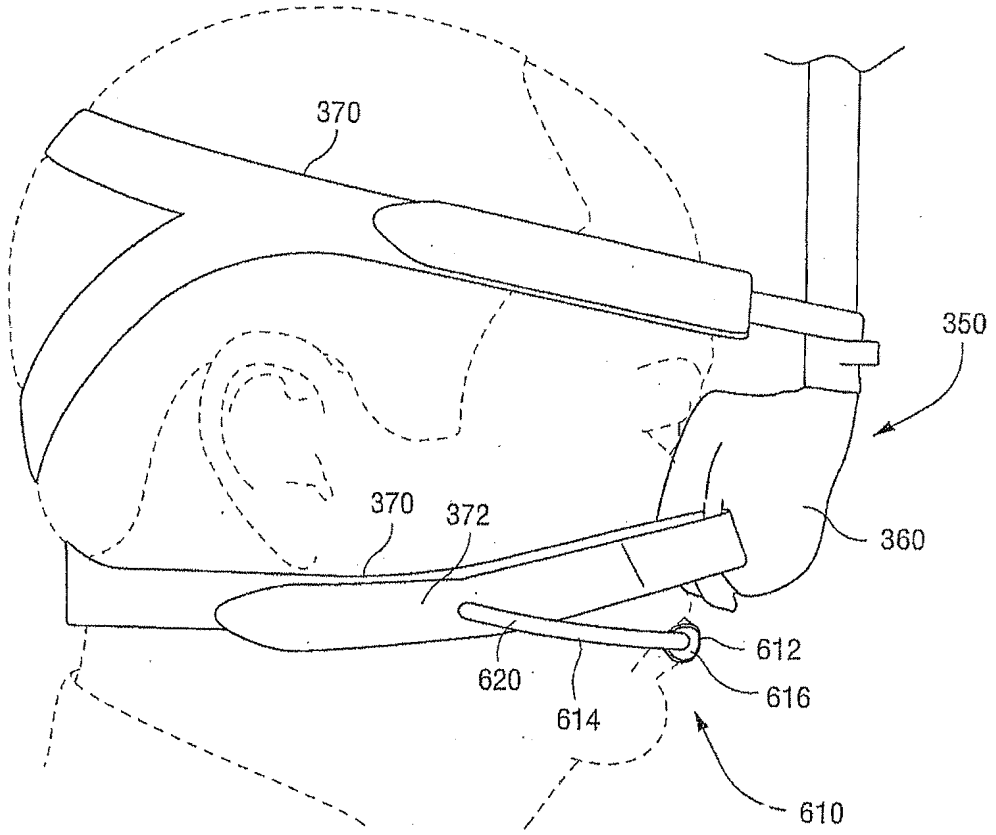


Fig. 16

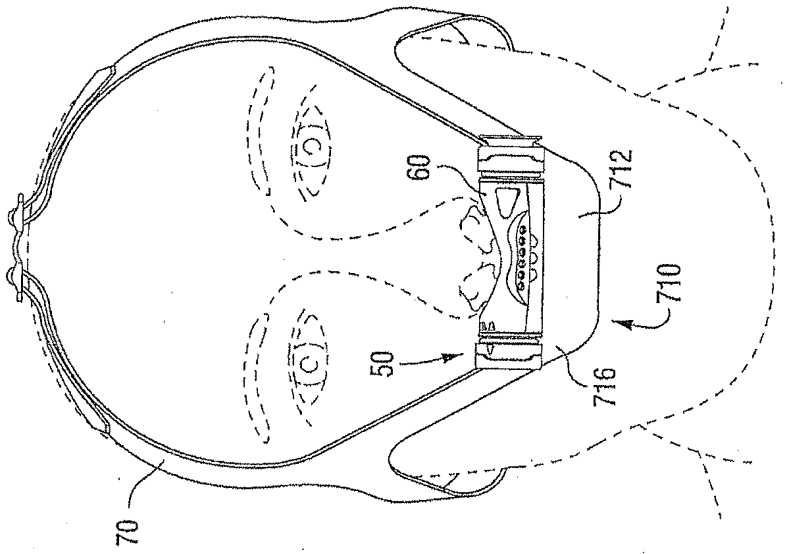


Fig. 18

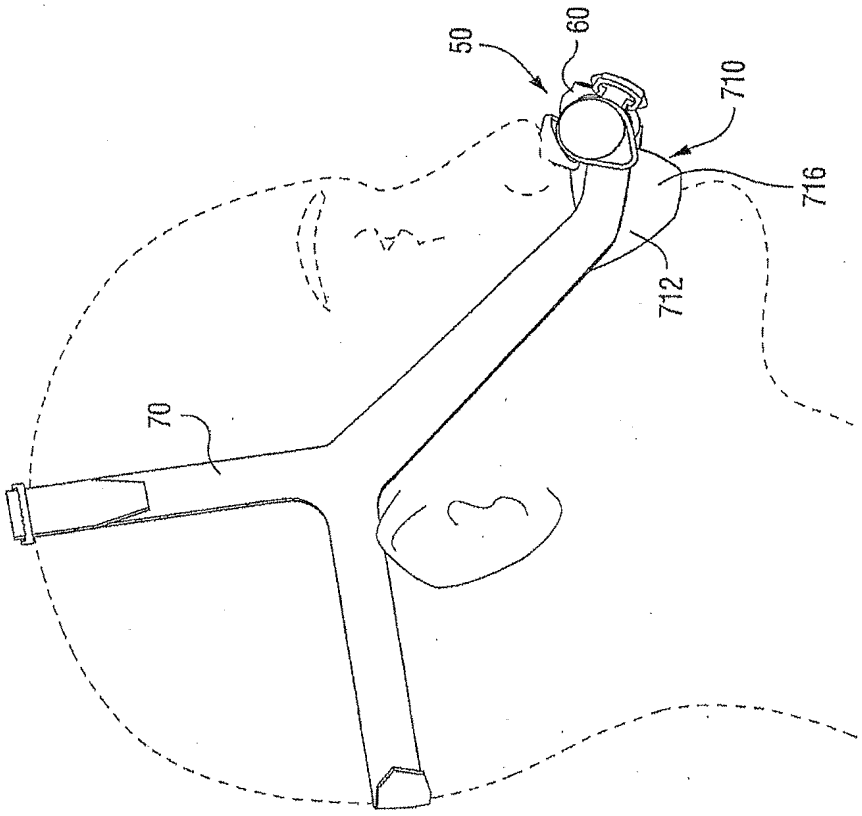


Fig. 17

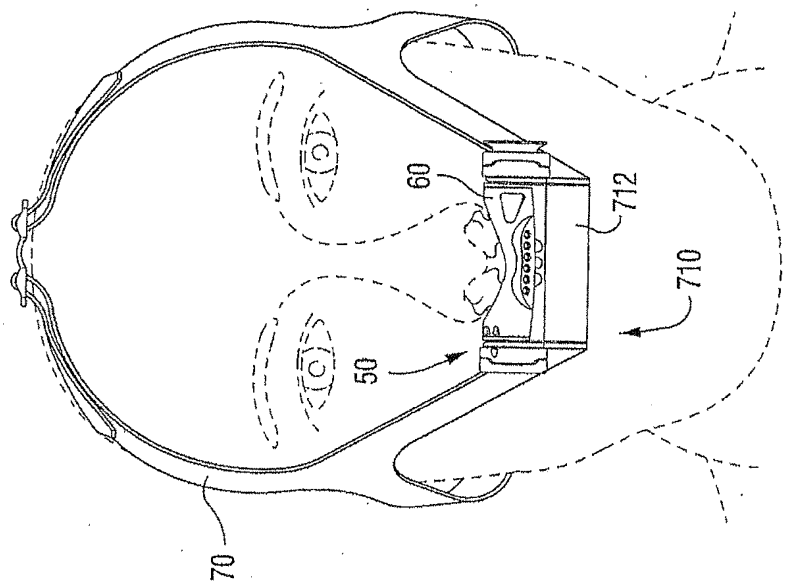


Fig. 20

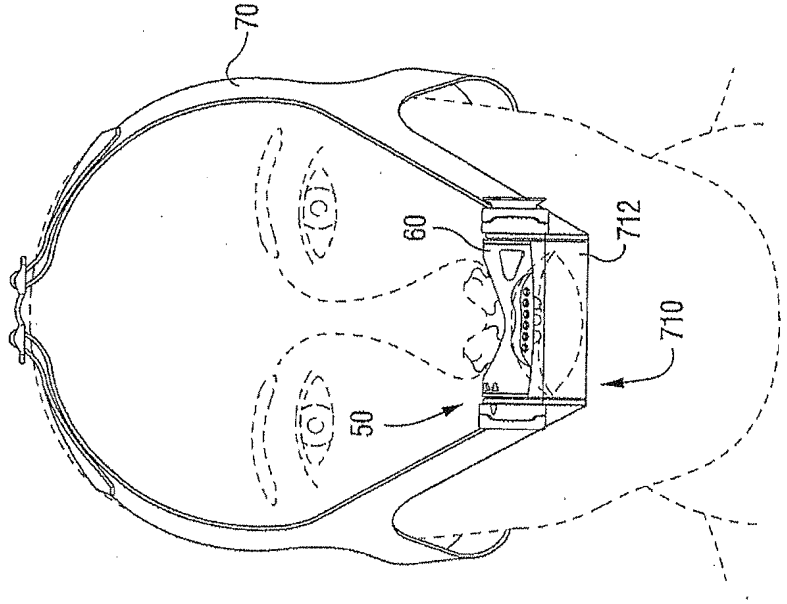


Fig. 19

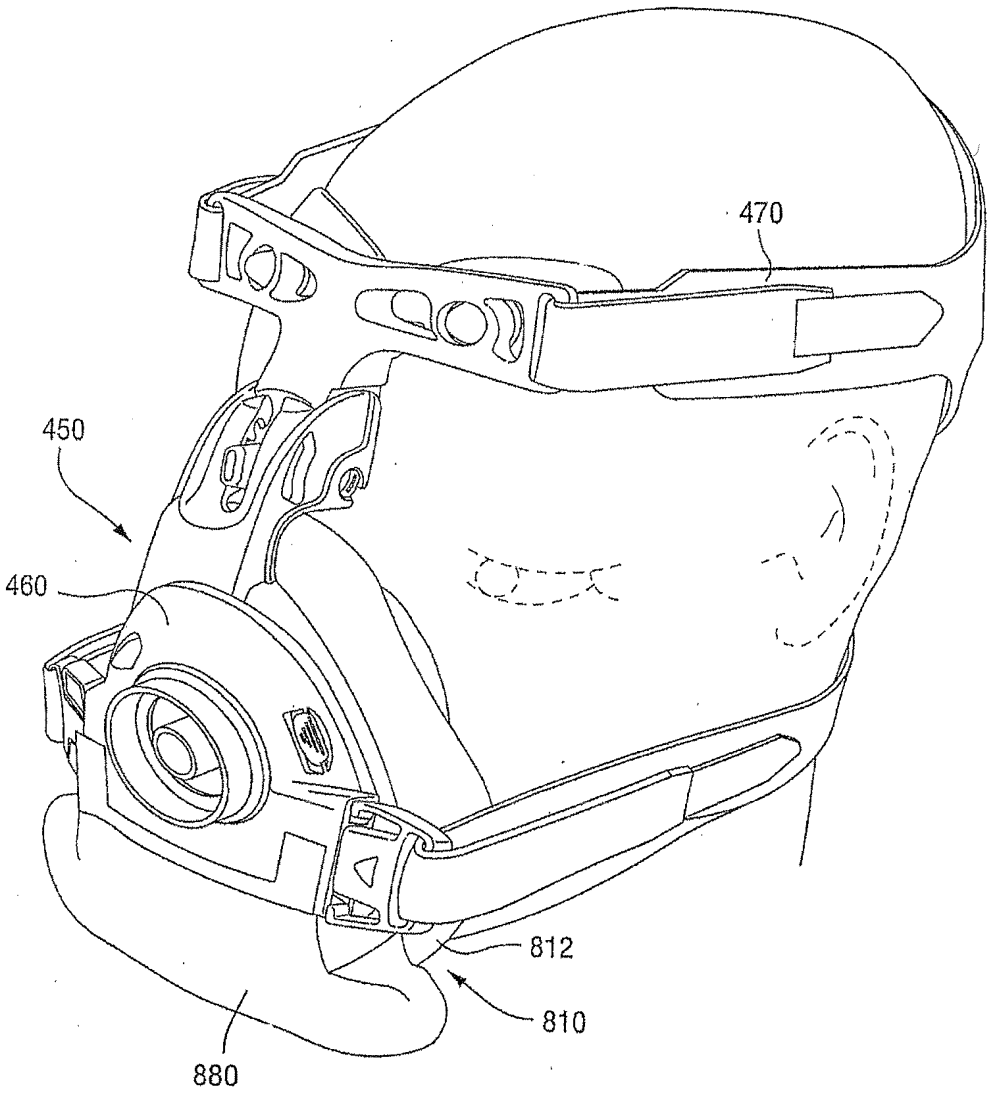


Fig. 21

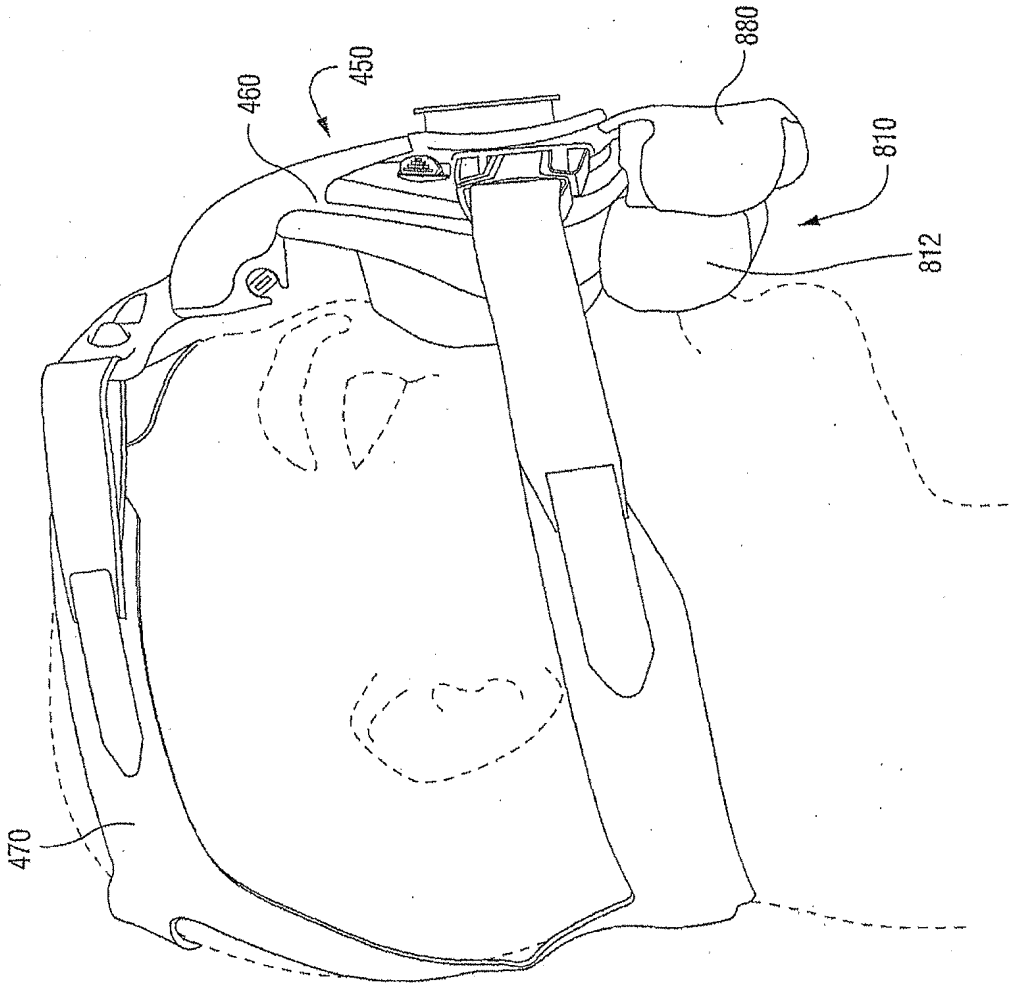


Fig. 22

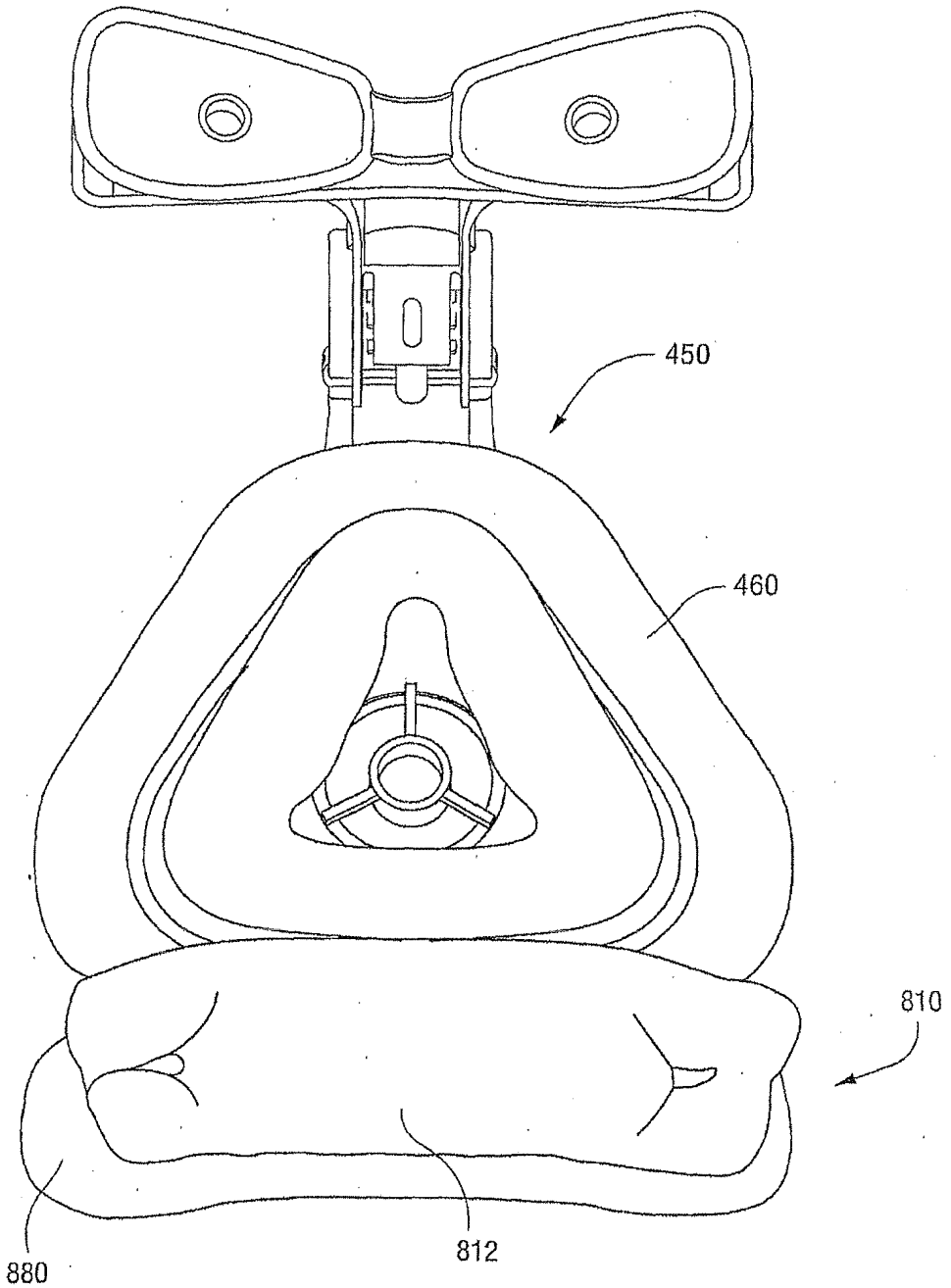


Fig. 23

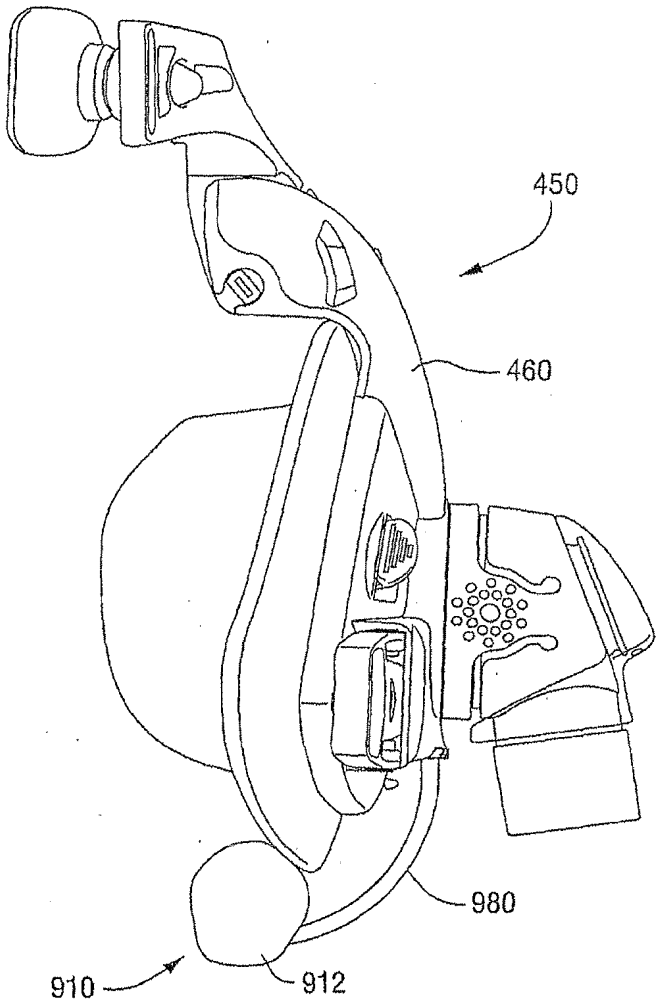


Fig. 24

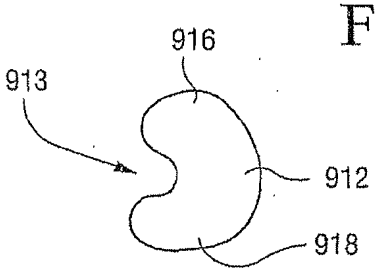


Fig. 25

Fig. 26

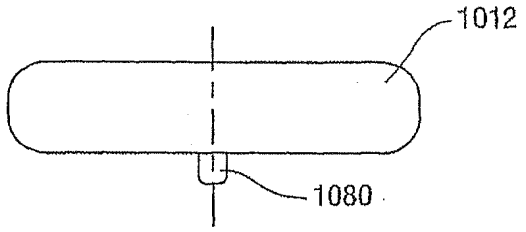


Fig. 27

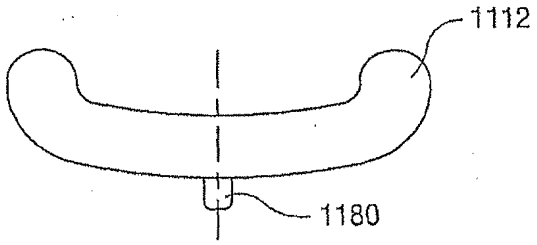


Fig. 28

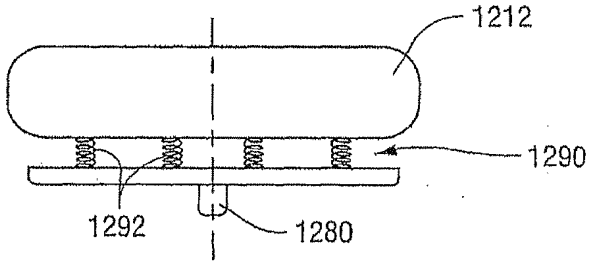


Fig. 29

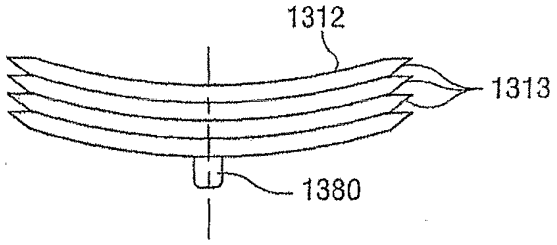
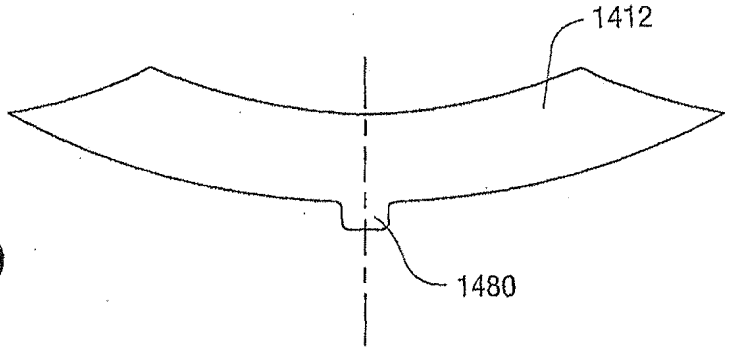


Fig. 30



INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2006/001246

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.

A61M 16/00 (2006.01) ***A62B 9/06*** (2006.01) ***A62B 18/08*** (2006.01)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
DWPI - IPC A61M/IC, A62B/IC; & keywords (CPAP, APAP, BIPAP, VPAP, +pnea, +pnoea, mouth, lip, oral, labi+, oro+, seal+, cover+, block+, gag, valve, inlet, intake, strap, belt, head, gear, band, fastener, foam, rubber, silicone, gel, spring, bellows, gusset, pleat, accordion)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	US 5,560,354 A (BERTHON-JONES et al.) 1 October 1996	1 to 11, 17 to 29
X	See in particular column 6 lines 14 to 21 and the figures.	
Y	See in particular safety valve (item 56)	12 to 16
	AU 2004100928 A4 (SLEEPZONE CPAP PRODUCTS) 23 December 2004	1 to 11, 17 to 29
X	See in particular the figures.	
Y	See in particular safety valve (items B and C)	12 to 16
	WO 2003/057293 A1 (PARKER et al.) 17 July 2003	1 to 11, 17 to 29
X	See in particular figure 4	
Y	See in particular one-way valve (item 30)	12 to 16

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
31 October 2006	6 NOV 2006
Name and mailing address of the ISA/AU	Authorized officer
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	**KAREN VIOLANTE** Telephone No : (02) 6283 7933

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2006/001246

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	WO 1999/061089 A1 (RESMED LIMITED) 2 December 1999	1 to 11, 17 to 29
X	See in particular figures 7 to 14	
Y	See in particular one-way valve assembly (items 84 and 86)	12 to 16
	US 746,869 A (MOULTON) 15 December 1903	1 to 11, 17 to 29
X	See in particular column 2 lines 88 to 99 and the figures.	
Y	See in particular figure 3	12 to 16
	GB 2,368,533 A (SMITHS GROUP PLC) 8 May 2002	
X	See in particular page 5 paragraph 3 and figures 5 to 11.	1 to 11, 17 to 29
	US 6,405,729 B1 (THORNTON) 18 June 2002	
X	See in particular the figures (item 24).	1 to 11, 17 to 29
	US 6,571,798 B1 (THORNTON) 3 June 2003	
X	See in particular the figures (item 24).	1 to 11, 17 to 29
	US 6,470,886 B1 (JESTRABEK-HART) 29 October 2002	1 to 11, 17 to 29
X	See in particular the figures.	
Y	See in particular figures 8 to 13 (items 19 to 22)	12 to 16
	The nasal mask system including headgear and a wire arrangement of US 6,470,886 is intended to be combined with the anti-asphyxia valve of any of US 5,560,354, AU 2004100928, WO 2003/057293, WO 1999/061089 or US 746,869.	

INTERNATIONAL SEARCH REPORT

International application No.
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Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

[See Supplemental Box]

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2006/001246

Supplemental Box
(To be used when the space in any of Boxes I to VIII is not sufficient)

Continuation of Box No: III

This International Application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept.

In assessing whether there is more than one invention claimed, I have given consideration to those features which can be considered to potentially distinguish the claimed combination of features from the prior art. Where different claims have different distinguishing features they define different inventions.

This International Searching Authority has found that there are different inventions as follows:

- Claims 1 to 16 are directed to a mouth seal assembly including an anti-asphyxia valve. It is considered that the anti-asphyxia valve comprises a first distinguishing feature.
- Claims 17 to 20 are directed to a mouth seal assembly including a tube and a strap. It is considered that both the tube configuration and strap arrangement comprises a second distinguishing feature.
- Claims 21 to 28 are directed to a mouth seal assembly including a mount to adapt the mouth seal assembly onto a nasal mask system and wherein the mouth seal is formed with foam. It is considered that the seal being formed of foam comprises a third distinguishing feature.
- Claim 29 is directed to a nasal mask system including a nasal mask, a mouth seal assembly, a mount to adapt the seal onto the nasal mask and wherein the seal includes a spring, bellows or gusset arrangement. It is considered that the spring, bellows or gusset arrangement comprises a fourth distinguishing feature.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art.

The only feature common to all of the claims is a mouth seal for use with a nasal mask system, wherein the seal is adapted to form a seal with the patient's mouth. However this common feature is generic in the art. This means that the common feature can not constitute a special technical feature within the meaning of PCT Rule 13.2, second sentence, since it makes no contribution over the prior art.

Because the common feature does not satisfy the requirement for being a special technical feature it follows that it cannot provide the necessary technical relationship between the identified inventions. Therefore the claims do not satisfy the requirement of unity of invention *a posteriori*.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/AU2006/001246

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
US	5560354	AU	48371/97	AU	64816/94	EP	0634186
		US	6123071				
AU	2004100928	WO	2006079149				
WO	03057293	AU	2002367274	US	2003121520		
WO	9961089	AU	31251/99	AU	42488/99		
US	746869						
GB	2368533						
US	6405729						
US	6571798						
US	6470886						

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX